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The development and feasibility of a culturally tailored Malaysian Diabetes Education Intervention using Motivational Interviewing (MY DEUMI) for people newly diagnosed with type 2 diabetes mellitus

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King's College London

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**The development and feasibility of a culturally
tailored *Malaysian Diabetes Education*
Intervention *using Motivational Interviewing*
(MY DEUMI) for people newly diagnosed with
type 2 diabetes mellitus.**

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This thesis is submitted to King's College London for the degree of
Doctor of Philosophy

Department of Psychological Medicine
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King's College London

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Abstract

People with diabetes have high levels of morbidity, mortality, a relatively poor quality of life and psychological distress. Diabetes self-management is recognised as the cornerstone of diabetes care, but diabetes self-management education has not yet been implemented in Malaysia. This thesis aims to develop and examine the feasibility of a group-based culturally tailored *Malaysian diabetes education intervention using motivational interviewing* for adults newly diagnosed with Type 2 diabetes (T2DM), the MY DEUMI intervention.

Firstly, a systematic review was conducted to identify current literature and randomised controlled trials (RCT) to support diabetes self-management for people with T2DM in the Asian Western Pacific region. The review suggested that the group-based educational approaches delivered with longer total contact hours are associated with improvement in metabolic control. There was also a suggestion that the use of practical or hands-on activities are associated with positive outcomes particularly on blood glucose control.

Secondly, a qualitative study of personal experiences of diabetes self-management for adults with T2DM in Malaysia was conducted using semi-structured interviews (N=17) in a primary care setting. The results revealed that there is a need for psychological support in diabetes care. Barriers to effective diabetes self-management include social factors (shame/stigma), attitude towards food and beliefs in complementary medicine.

Thirdly, findings from the systematic review, semi-structured interviews and a scoping study to identify available culturally sensitive materials were then integrated to inform the development of the intervention. The intervention is underpinned by the Theory of Planned Behaviour and Social Cognitive Theory. The intervention manual was further adapted to be delivered using the motivational interviewing techniques.

Following recruitment of people with newly diagnosed T2DM from primary care clinics and community centres in Malaysia, the MY DEUMI intervention was evaluated in a small pre-post feasibility study (N=30). The result indicates evidence of feasibility for the intervention and a positive impact on metabolic control and self-efficacy. Moreover, the study suggests that the group-based approach for the delivery of diabetes education is acceptable among the multicultural community in Malaysia. Exit interviews suggested that participants valued the psychological approach which helped improve self-efficacy for their diabetes self-management.

Dedicated to:

My soulmate (Redzuan A.)

My Parents (Mr Mohamed A., Mrs Norazan I.)

My Mother in law (Mdm Mariammah S.)

My bundles of joy (Areedz Shah R. & Hanna Arishah R.)

My siblings (Ali Asyraf M., Nurul Asyiqin M., Ariff Asyraf M.)

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DECLARATION FOR ACADEMIC (PhD) THESIS

I, Arbaktun Mardiah Mohamed, declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

The project report of ‘The development and feasibility of a culturally tailored Malaysian Diabetes Education Intervention using Motivational Interviewing (MY DEUMI) for people newly diagnosed with type 2 diabetes mellitus’ was written under the supervision of Dr Kirsty Winkley and Prof Khalida Ismail.

I further certify that:

- i. this work was done mainly while in candidature for a research degree at this University;
- ii. where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
- iii. where I have consulted the published work of others, this is always clearly attributed;
- iv. where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
- v. parts of this work have been published as: Mohamed, A.M., Romli, J., Ismail, K. & Winkley, K., 2017, Barriers to and facilitators of effective diabetes self-management among people newly diagnosed with Type 2 diabetes mellitus (T2DM): A qualitative study from Malaysia (Abstract). In: Proceedings of Society for Social Medicine 61st Annual Scientific Meeting 2017, Journal of Epidemiology & Community Health;71(Suppl 1): A68.

Signed: 

Date:5/07/2019.....

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Glossary of Abbreviations

AADE	American Association of Diabetes Educators
ACCORD trial	Action to Control Cardiovascular Risk in Diabetes trial
ADA	American Diabetes Association
ADVANCE trial	Action in Diabetes and Vascular Disease: Preterax and Diamicon Modified Release Controlled Evaluation trial
AIDS	Acquired immune deficiency syndrome
AWP	Asian Western Pacific
BMI	Body Mass Index
CAM	complementary and alternative medicine
CBT	cognitive behaviour therapy
CD	communicable disease
CHD	coronary heart disease
CI	confidence interval
CVD	cardiovascular disease
DCDCP	Diabetes Care Data Collection Project
DESMOND	Diabetes education and self-management for ongoing and newly diagnosed
DFU	diabetic foot ulcers
DiRECT	Diabetes Remission Clinical Trial
DMSES UK	Diabetes Management Self-Efficacy Scale United Kingdom
DSME	diabetes self-management education
DSMES	diabetes self-management education and support
DSMP	Diabetes Self-Management Program
DSMQ	Diabetes Self-Management Questionnaire
EASD	European Association for the Study Diabetes
ES	effect size
FPG	fasting plasma glucose
GDP	gross domestic product
GI	glycaemic index
GP	general practitioner
HbA1c	glycated haemoglobin
HeLP-Diabetes	Healthy Living for People with Diabetes
HIV	human immunodeficiency virus
HLF	Healthy Lifestyle Facilitator (HLF)
HTA	Health Technology Appraisal
IDF	International Diabetes Federation
IFCC	International Federation of Clinical Chemistry
IFG	impaired fasting glucose
IGT	impaired glucose tolerance
IPSE	International Partners in Self-management and Empowerment
IQR	interquartile range
KCL	King's College London
KPJ	'Kumpulan Perubatan Johor' (A Member of Johor Corporation Group)
KRT	'Rukun Tetangga'
LOCF	last-observation-carried-forward
M	Mean
MI	motivational interviewing

MOH	Ministry of Health Malaysia
MOVE-IT	M otivational Interviewing I ntervention
MR	meal replacement
MRC	Medical Research Council
MREC	Medical Research and Ethics Committee
MY DEUMI	M alaysian d iabetes e ducation intervention using m otivational interviewing
NCD/s	non-communicable disease/s
NGSP	National Glycohaemoglobin Standardisation Programme
NGT	normal glucose tolerance
NHMS	National Health and Morbidity Survey
NICE	National Institute for Health and Clinical Excellence
NIH	National Institutes of Health
OBE	outcome-based education
OHA/s	oral anti-hyperglycaemic agent/s
PNM	Psychiatry, Nursing and Midwifery
PRIDE	P artner to I mprove D iabetes E ducation
PRISMA	Preferred Reporting Items for Systematic Review
RCT/s	randomised controlled trial/s
RESC	Research Ethics Subcommittee
RM	Ringgit Malaysia
RR	relative risk
SIGN	Scottish Intercollegiate Guidelines Network
SCT	Social Cognitive Theory
SD	standard deviation
SDE	structured diabetes education
SEA	Southeast Asia
SLT	Social Learning Theory
SOS	The Swedish Obesity Study
T1DM	type 1 diabetes mellitus
T2DM	type 2 diabetes mellitus
TPB	Theory of Planned Behaviour
UAE	United Arab Emirates
UK	United Kingdom
UKPDS	UK Prospective Diabetes Study
US/USA	United States/ United States of America
USD	US Dollar
VAT	visceral adipose tissue
WC	waist circumference
WHO	World Health Organization

Chapter 1 : Type 2 Diabetes Mellitus and it's management in Malaysia

1.1 Chapter Scope

This introductory chapter is divided into 5 sections relevant to the research area of the thesis, which is to develop education for people with Type 2 diabetes in Malaysia. First, it describes the population profile of Malaysia including its health characteristics. Second, it discusses the pathogenesis of Type 2 diabetes mellitus (T2DM). This is followed by the third section, the risk factors for people with T2DM in Asia and Malaysia. Fourth, it introduces the non-pharmacological (lifestyle modification) and the pharmacological management of T2DM. Next, it discusses the importance and roles of diabetes self-management education (DSME) for people with T2DM. Finally, the role of the researcher in the development of a new education programme for T2DM in Malaysia is discussed.

1.2 Population profile of Malaysia and health characteristics

1.2.1 A profile of Malaysia

Malaysia was established on 16th September 1963 and constitutes states that were formerly under the British rule. The Federation of Malaya gained independence in August 1957 and became a member of the Commonwealth Countries. The modern country of Malaysia is located in South East Asia (see Figure 1), within the Western Pacific region.

Figure 1: Map showing the countries and regions of South East Asia with borders, main cities and capitals.



Adapted from (Nations Online Projects, 2018b).

Malaysia consists of 13 states known as *Negeri* and three federal territories, named *Wilayah Persekutuan Kuala Lumpur*, *Putrajaya* and *Labuan*. Malaysia is divided into Peninsular and East Malaysia (Sabah and Sarawak) by the South China Sea with a total landmass of 329, 847 square kilometres (127, 350 square miles) (see Figure 2). In 2017, the total population of Malaysia was 32 million. Malaysia has a multicultural society in which 67% are Malays, 23% are Chinese, 7% are Indians and the rest are made up of Bumiputera (aboriginal people) and other minority ethnic groups. *Bahasa Melayu* (the Malay language) is the national language, other mother tongue languages practised include Mandarin and Tamil, and English is widely used as a second language.

Figure 2: Map showing Malaysia and the surrounding countries with international borders, state boundaries, the national capital Kuala Lumpur, state capitals, and major cities.



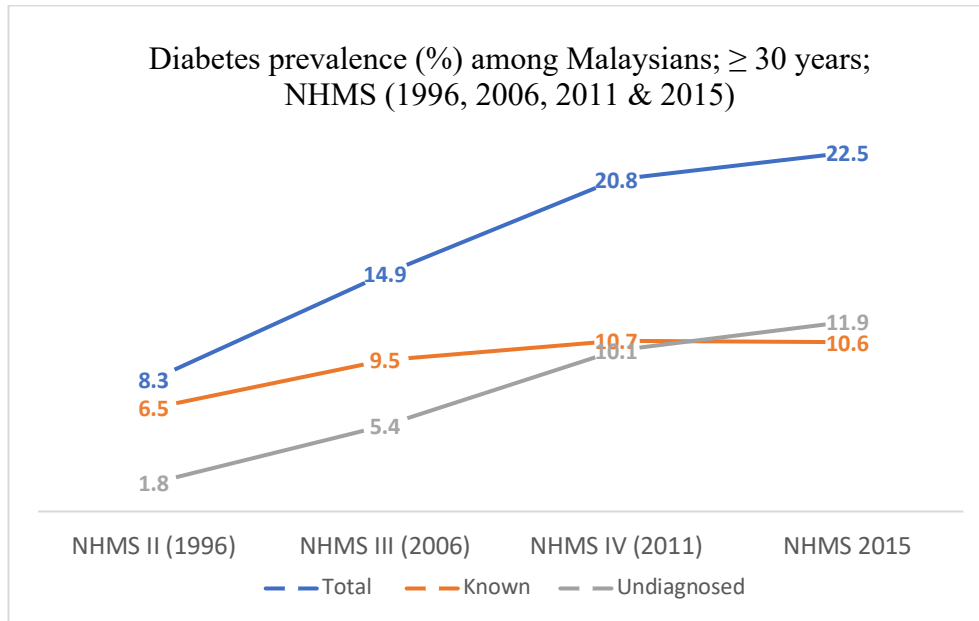
Adapted from (Nations Online Projects, 2018a).

1.2.2 Current burden of diabetes in Malaysia

Recent urbanisation and shifting demographic patterns have influenced health and healthcare services in Malaysia. Generally, the health status amongst the local community has dramatically improved over the last decade and the challenge has shifted from the treatment of infectious/communicable disease (CD) to non-communicable diseases (NCDs). Life expectancy increased between 1990 and 2016 from 68 years to 73 years for males, and from 72 years to 77 years for females, and overall from 70 to 75 years (Department of Statistics Malaysia, 2016). Despite better life expectancy from birth the increasing prevalence of NCDs, such as chronic disease, contributes to 73% of mortality rate, and has raised the government's concern (WHO, 2014). The mean age of diagnosis for T2DM among Malaysian is 53 years, and the premature mortality due to chronic disease (cancer, diabetes and chronic respiratory disease) is 20% amongst adults aged between 30 and 70 years (Institute for Public Health, 2015). For this reason, both healthcare professionals and the community must work together to reduce the burden of disease in Malaysia.

As the population in Malaysia increases owing to economic development, there is a growing number of people with T2DM, and the government needs to act to reduce the burden of the disease. The National Health and Morbidity Survey (NHMS) Malaysia showed an increased prevalence of diabetes among adults aged above 30 years from 6.3% in 1986 (NHMS I), 8.3% in 1996 (NHMS II), 14.9% in 2006 (NHMS III) to 20.8% in 2011 (NHMS IV) and 22.5% (NHMS 2015) (Institute for Public Health, 2011, 2015) (see Figure 3).

Figure 3: Trend of diabetes among Malaysian adults, aged more than 30 years (National Health Morbidity (NHMS) (1996, 2006, 2011 and 2015))



This dramatic increase in diabetes prevalence is responsible for the associated burden of diabetes complications, such as renal failure among the Malays and diabetic foot ulcers (DFU) among the Indians in Malaysia as reported in the Diabetes Care Data Collection Project (DCDCP) study. Around 1% of those who attended follow-up regularly required dialysis, and 1.9% had a lower extremity amputation (Zaini, 2000) resulting in a poor quality of life and an increased healthcare cost. According to the National Kidney Transplant report, 61% of end-stage renal failure cases among Malaysian are secondary to diabetes (Goh *et al.*, 2014) and the Malaysian National Diabetes Registry reported that prevalence of DFU is about 11% among people with T2DM (Mustapha and Azmi, 2013).

The 2013 Malaysian diabetes clinical audit revealed that the prevalence of diabetes complications are 9% for diabetic nephropathy, 7.5% for retinopathy, 5.32% for ischemic heart disease, 12.8% cerebrovascular diseases and 1.28% for diabetes

foot ulcer (Mustapha and Azmi, 2013). Another retrospective cohort study in Malaysia (N=249) investigating the factors associated with the diagnosis of coronary heart disease (CHD) among people with T2DM, has reported that 79% had retinopathy, 32% had nephropathy, 8.0% had neuropathy and 4% had a stroke and 12% of the participants developed CHD after 6 years of being diagnosed with T2DM (Wan Ibrahim *et al.*, 2013). In addition, the cohort study reported the main significant diagnostic factor of CHD among people with T2DM was the incidence of stroke (Adjusted hazard ratio=3.72, 95% confidence interval (CI) [1.41,9.77], $p = 0.008$). In a nutshell, not only are these complications personally devastating for those affected, they also have high healthcare costs associated with them though some can be prevented.

According to the World Bank in 2014, Malaysia's gross domestic product (GDP) was around 26.9 billion US Dollar (USD), and it spent about 4.2% of its GDP on health (WHO, 2016). A cost analysis study which aimed to estimate the cost of diabetes across the globe (Zhang *et al.*, 2010), reported that Malaysia spent more than USD 600 million in 2010 on diabetes, which is equivalent to 16% of the total allocated health budget. The study indicated that Malaysia is within the top 10 countries in the world in terms of money spent on diabetes. On the other hand, there is a discrepancy in expenditure for diabetes care worldwide where developed countries usually spend more with smaller numbers of people with diabetes, for example, the United States of America (USA) spends around 7,383 USD per person with diabetes compared to Malaysia with 325 USD. In a local economic analysis study conducted in 2017, it was estimated that the total cost of diabetes is heavily incurred by the government (Mustapha *et al.*, 2017). It was estimated in the study that around 2 billion *Ringgit Malaysia* (RM) is spent on diabetes care and half of that is subsidised by the government.

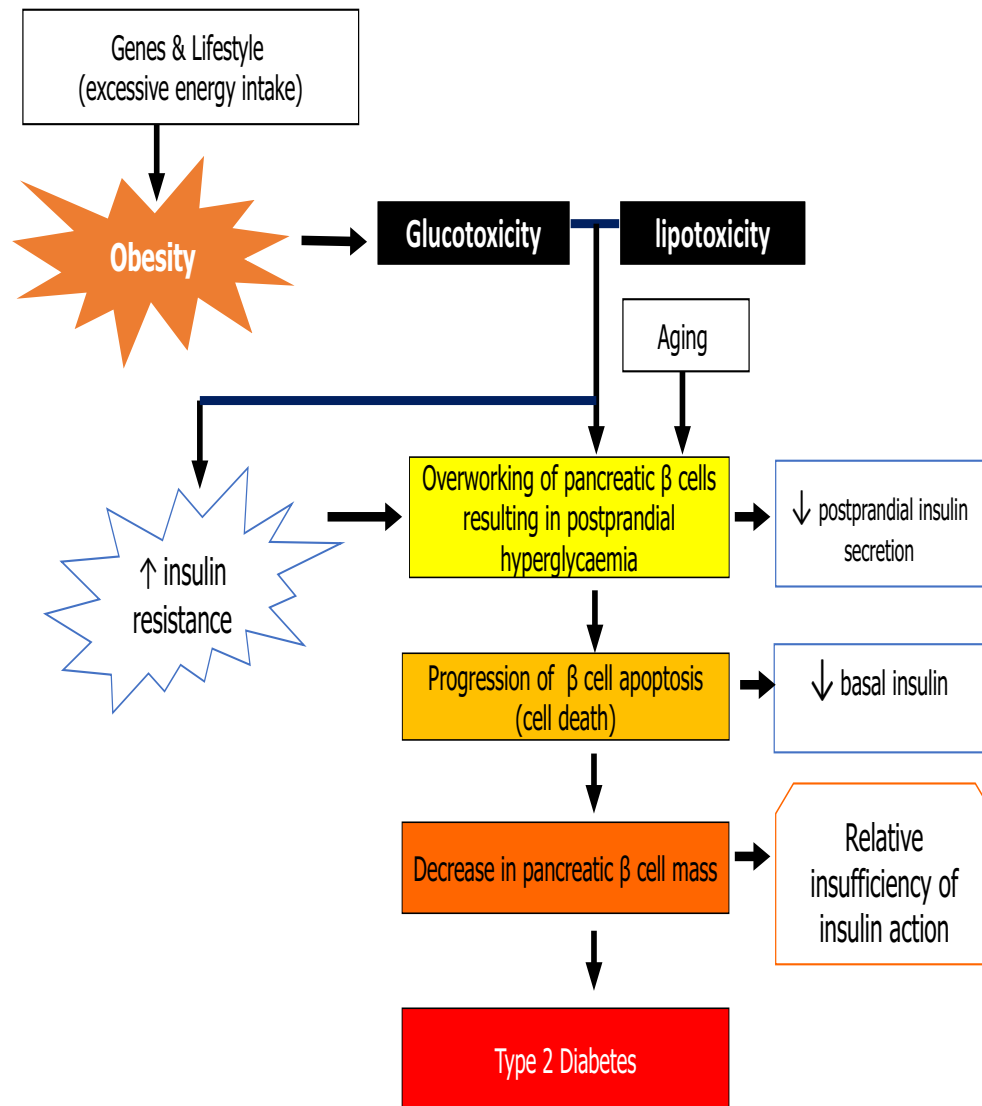
1.3 Type 2 Diabetes Mellitus

1.3.1 Pathophysiology (Insulin response and disease progression)

Type 2 diabetes mellitus is an umbrella term for a group of metabolic disorders that cause blood glucose levels to rise resulting from the insufficient action of insulin and insulin resistance (Kaku, 2010). The body cells use glucose as fuel to energise all the organs. However, glucose cannot be utilised until the insulin (a hormone) produced by beta cells in the pancreas, acts as a key to unlock the cell door to allow glucose to enter. Following a meal containing carbohydrates, blood glucose levels rise (hyperglycaemia), and the pancreas stimulates insulin secretion for glucose uptake by the cell to balance glucose levels in the bloodstream.

People with T2DM have frequent and persistent hyperglycaemia because the body is incapable of maintaining a healthy level of glucose in the blood. This is for 2 main reasons, namely insulin insufficiency and insulin resistance. Prolonged and persistent hyperglycaemia caused by insulin resistance results in metabolic malfunctioning of the liver and skeletal muscle, thus insulin insufficiency occurs as a result of an increased insulin demand (Kumar et al. 2010). Figure 4 summarises the process that leads to problems with insulin regulation in an individual and the progression towards T2DM.

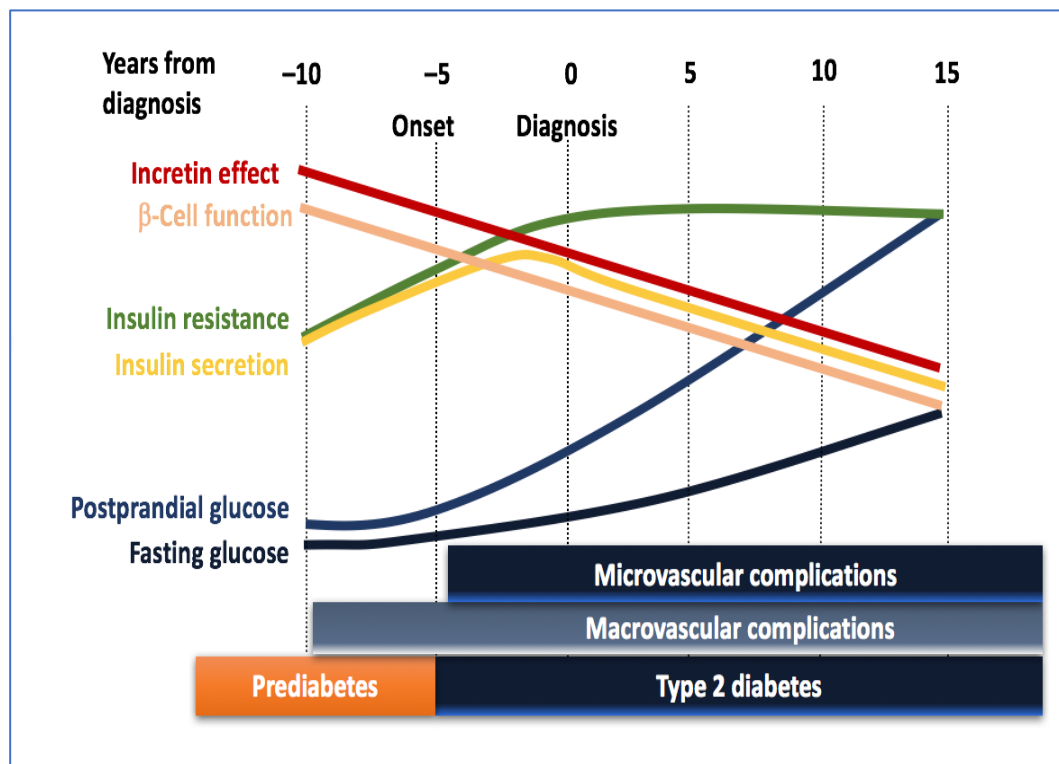
Figure 4: An overview of type 2 diabetes mellitus (T2DM) pathology.



Natural history of type 2 diabetes

The pathogenesis of T2DM has been evaluated in studies that investigate the relationship between insulin resistance and impaired insulin secretion. For example, a longitudinal study among Pima Indians (Indigenous Americans) in Southern Arizona who have a high prevalence of diabetes demonstrated that their glucose tolerance deteriorated from normal glucose tolerance (NGT) to impaired glucose tolerance (IGT) to diabetic state over 5.1 ± 1.4 years (Weyer et al., 1999). People with T2DM should be informed that this disease does not always have slow progression but may rapidly progress if it is not well controlled and treated. Figure (5) gives a conceptual representation and explains the changes in the level of insulin secretion and sensitivity from the NGT state followed by IGT and diagnosis of T2DM.

Figure 5: The natural history of insulin resistance, progressing from impaired glucose tolerance to overt T2DM.

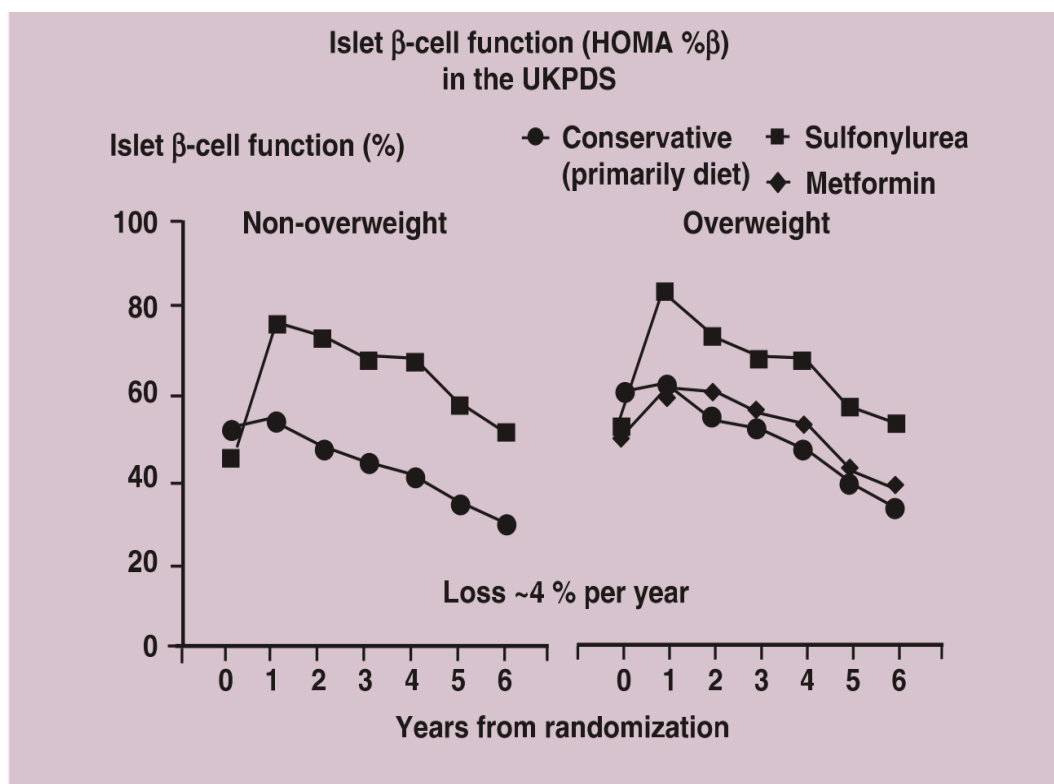


Adapted from (Ramlo-Halsted and Edelman, 1999; Nathan, 2006; Home, 2008)

Initially, the β -cells are compensated through the hypersecretion of insulin and the fasting glucose level remains near to normal. Clinically, this stage is referred to as the impaired fasting glucose (IFG) and IGT and is essentially asymptomatic but is categorised as the pre-diabetic stage characterised by mild hyperglycaemia. However, with time, the β -cell mass deteriorates due to apoptosis and insulin secretion starts to fall, causing the post-prandial glucose level to rise, and followed subsequently by the fasting glucose level. Eventually, marked hyperglycaemia is evident and with-it insulin resistance and this is when type 2 diabetes is diagnosed. Gradually, poor metabolic control and persistent hyperglycaemia can cause further destruction of the β -cells, and microvascular complications may be experienced due to metabolic impairment (UK Prospective Diabetes Study Group, 1998; Ramlo-Halsted and Edelman, 1999; Nathan, 2006).

However, disease progression is associated with the progression of β -cell failure even with good metabolic control, as supported by the findings of the United Kingdom (UK) Prospective Diabetes Study (UKPDS) (Figure 6). In 1995, the UKPDS trial reported that intensive treatment with antidiabetic agents significantly improved glycaemic control however there was still evidence of deterioration of β -cell function over 6 years.

Figure 6: The progressive decline of β -cell function in the UKPDS (non-overweight n=887; overweight n=269).



Adapted from a slide based on UKPDS data taken from the WorldWIDE slide resource (Worldwide Initiative for Diabetes Education, no date).

Furthermore, it is not only prolonged insulin resistance and insulin deficiency that contribute to T2DM—obesity, genetic factors, family history, diet and sedentary lifestyle also play a role as reported in a review of diabetes risk factors in Asia (Asia Pacific high income : Japan, South Korea, Singapore; East Asia: China, Hong Kong, North Korea; South Asia: Bangladesh, India, Nepal, Pakistan; Southeast Asia: Indonesia, Malaysia, Philippine, Sri Lanka, Thailand, Vietnam) (Weber *et al.*, 2012). Therefore, to prevent the onset of T2DM, educational interventions to prevent diabetes should target people at high-risk and this is discussed in the next section.

1.4 Disparities of type 2 diabetes mellitus risk factors for Asians and Malaysians

Identifying and understanding the key risk factors associated with T2DM is crucial for the development of efficient policies to treat and prevent it where possible.

1.4.1 Overweight and obesity

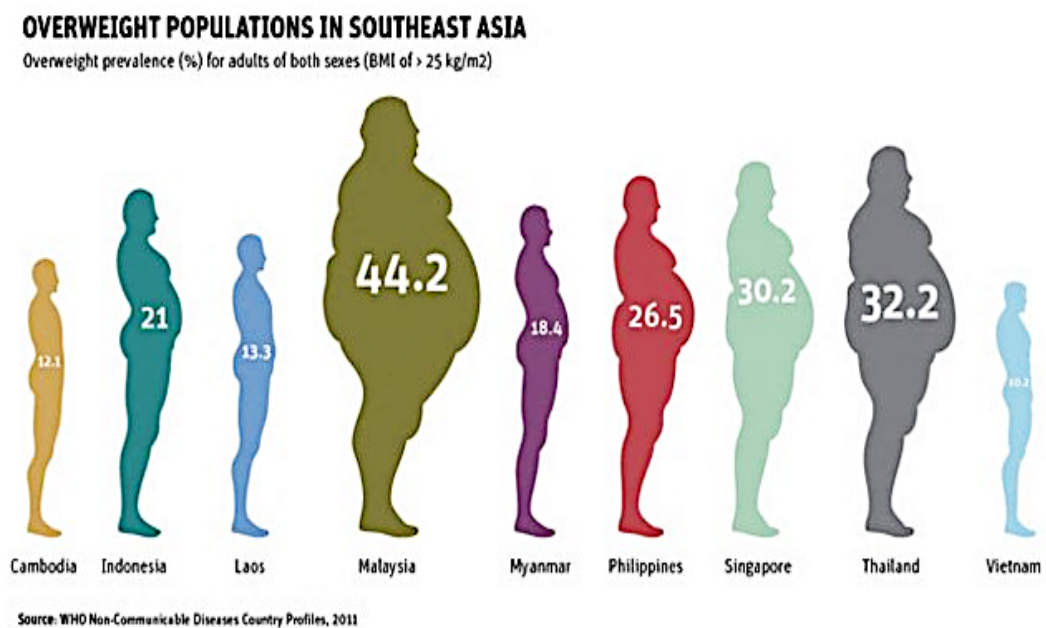
Overweight and obesity could result in inflammation and endoplasmic reticulum stress, leading to insulin resistance in the liver and skeletal muscle. Poor management of obesity, or late detection, increase the risk of getting T2DM (Weber *et al.*, 2012). According to the conventional definition of Body Mass Index (BMI) $\geq 25 \text{ kg/m}^2$ = overweight; $\geq 30 \text{ kg/m}^2$ = obesity. Generally, Asians have lower rates of obesity than the Westerners. However, an epidemiological review study reported that the prevalence of diabetes is higher among Asians compared to the Caucasians (USA=8.2%; India=12.1%; Taiwan=9.2%; Hong Kong=9.8%; Singapore 8.4%; Thailand=11.9%) with a younger age at diagnosis and earlier onset of diabetes complications (Yoon *et al.*, 2006).

Furthermore, a comprehensive review of 21 countries (N=263,000) where 73% were Asians from 11 countries in the Asia-Pacific region confirmed that Asians are more likely to develop T2DM compared to the Caucasians. It demonstrated that with the same BMI of 24 kg/m^2 the proportion of Asian men diagnosed with diabetes was 5% higher compared to the Caucasians at 2%, while for women the values were 5% and 1% respectively (Huxley *et al.*, 2007). The findings highlighted the fact that Asians are at risk of developing diabetes at a lower BMI as compared to the Caucasians. However, another cross-sectional study with a large pooled population (N=900, 000) across several countries of South (India and Bangladesh) and East Asia

(China, Japan, Korea, Singapore and Taiwan) concluded that other risk factors such as socioeconomics, urban residence, education level and country were associated with BMI and diabetes prevalence and explained that diabetes in Asia is not dependent on the BMI alone (Boffetta *et al.*, 2011). Figure 7 is an infographic presenting the prevalence of overweight population in South East Asia.

The adoption of sedentary lifestyles and an increased availability of cheap, processed food are thought to be the main drivers of obesity in Malaysia. The NHMS in 2006 demonstrated a sharp rise in obesity prevalence from 4.4% to 14% over a 10-year period (Institute for Public Health, 2011). Poor management of obesity or late detection increases the risk of T2DM development, as demonstrated in a review of prevalence, risk factors and behavioural intervention among people with T2DM in Asia (East Asian, Southeast Asia, South Asia and Southwest Asia) and Asian migrant populations (Weber *et al.*, 2012).

Figure 7: The infographic is presenting the prevalence of overweight populations across South East Asia countries.



Adapted from website page (Karaman, 2014).

Obesity is an established risk factor for T2DM, and a high composition of abdominal fat increases the likelihood of insulin resistance. A review study aimed at investigating the relationship and differences between body fat and BMI among different groups of Asians (Malay and Chinese from Indonesia; Malay, Chinese and Indian from Singapore and Chinese from Hong Kong) concluded that the Indians had the highest body fat percentage, followed by the Malays and the Chinese as they tend to develop diabetes at a lower BMI than the Caucasians, and suggested that a universal BMI cut-off point is not an appropriate measure for Asians (Deurenberg, Deurenberg-Yap and Guricci, 2002). To explain this, Asians who have the same BMI as Caucasians, have more visceral adipose tissue which is also associated with T2DM. Furthermore, a cross-sectional analysis of 4136 adults from the Singapore Prospective Study Project demonstrated that the Indians were the most insulin resistant, the Malays were at the intermediate level, while the Chinese were the least resistance (Gao *et al.*, 2012). Weight management interventions may therefore need to vary according to ethnic groups since there are differences in fat distribution, adiponectin level and inflammatory markers.

Body fat distribution

Central or abdominal obesity measured by waist circumference (WC) is a useful measure of obesity-related risk of T2DM among adults with normal BMI. This characteristic reflects the excessive fat accumulation in the muscle tissue and liver, which is known as the endocrine organ, that will lead to insulin resistance and an increased glucose intolerance causing metabolic impairment (Despres, 2012).

The largest obesity prevalence study aimed to investigate the association between fat distribution using WC in primary care settings across 63 countries (170,000 individuals) demonstrated that among lean individuals (BMI <25kg/m²), for men and women, there is a 29% and a 48% increase in the WC measurement (>102/88cm, men/women) respectively, of which 13% and 11 % had diabetes and 16% and 13% had cardiovascular disease (CVD) suggesting that WC is highly associated with diabetes and CVD (Balkau *et al.*, 2007). This was also supported by a trial assessing the visceral adipose tissue (VAT) via imaging technology (computed tomography scan) among healthy Chinese, South Asian and Caucasians, which demonstrated that at the same BMI and WC Asians had more VAT than the Caucasians (Lear *et al.*, 2007).

Sedentary lifestyle (lack of physical activity)

Urbanisation and technological development have reduced physical activity amongst many Asians. Fewer people cycle or use public transportation, and there is more dependence on motorised vehicles. For example, compared with the last decade in Beijing China, 1 in 10 Beijing residents owns a car replacing the bicycle as the former primary mode of transportation (Wang *et al.*, 2007). While in India, there is an increasing rate of motor vehicle purchasing, which is at 11% annually (Narayan and Kinra, 2008).

Findings from a systematic review and meta-analysis of 18 prospective studies to determine the association of sedentary lifestyle (sitting behaviours) and diabetes demonstrated that longer sitting hours was associated with 112% increase in the relative risk (RR) of diabetes (RR 2.12; 95% (CI) [1.61-2.78]) (Wilmot *et al.*, 2012). In Malaysia, over 60% of adults are sedentary, as reported by the WHO (WHO, 2010),

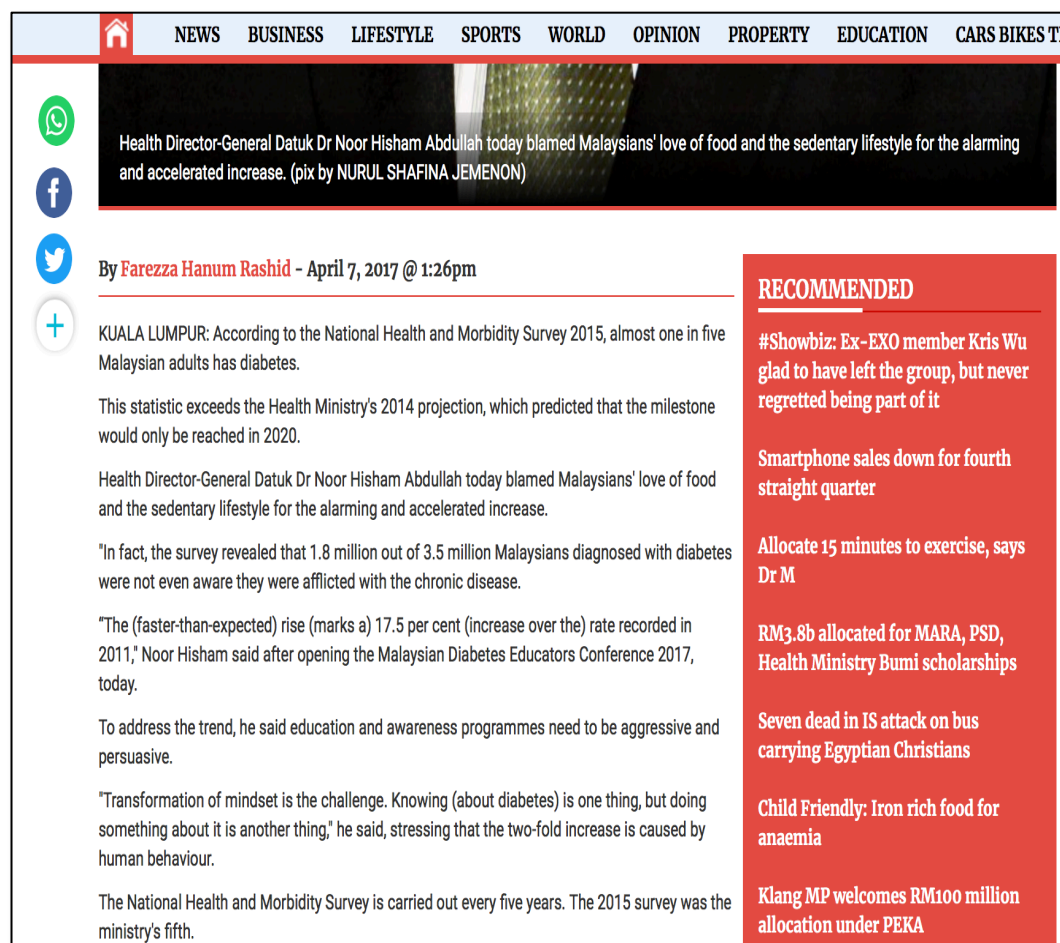
and a descriptive study investigated the socio-demographic factors associated with physical activity among adults in 3 Malaysian states (N=770) demonstrated that younger males were generally active for both moderate and vigorous type of exercise, however, educated Malaysians are less active (Lian *et al.*, 2016).

1.4.2 Cultural influences on perceptions and management of diabetes.

From the health professional perspective, it is recommended that chronic disease management should involve multiple components including medical therapy, diabetes self-management education, and effective communication with the patient. Health information should be available to support individuals to self-manage their chronic disease (Institute of Medicine, 2001). However, people with diabetes who do not restrict themselves to these components when it comes to managing their condition and flexibility may promote motivation to maintain optimum diabetes self-management and this can be achieved through empowerment and increasing self-efficacy. Apart from that, health professionals should appreciate that culture is an important influence of diabetes self-management.

The countries of Southeast Asia (SEA)—Indonesia, Malaysia, Singapore, Brunei, Thailand, Myanmar, Laos, Cambodia, Vietnam and the Philippines—are diverse in terms of ethnicities, politics, economics, health systems, resources, culture and religious beliefs. Therefore, people with diabetes manage their condition within a specific cultural landscape, and they are more often than not, influenced by particular cultural norms. An illustration of this is a Malaysian newspaper cutting (Figure 8) which highlights the rising prevalence of diabetes in Malaysia relative to its food-centric culture and sedentary behaviour.

Figure 8: A local Malaysian newspaper cutting highlighting the rising prevalence of diabetes due to Malaysians' food-centric culture and lack of physical activity.



Adapted from (Rashid, 2017).

Rapid urbanisation among SEA countries has led to the improvement of infrastructure, technology and food supply. As a result, Asians have changed their traditional dietary pattern and become more sedentary. In Thailand, a review of nutritional transition and health morbidity and mortality revealed that there is an increased intake of animal fat, take away and ready-to-eat food among local Thais, and this change has significantly increased the risk of cardiovascular disease and obesity (Kosulwat, 2014). However, in addition to urbanisation cultural beliefs and practices may also promote behaviour that makes successful diabetes self-management difficult.

For example, qualitative studies in Malaysia and Thailand have revealed that Thai and Malaysian lay terms for diabetes mellitus are “bao waan” and “kencing manis”, respectively (literally meaning sweet urine). It has been suggested these terms may have given people with diabetes the idea that all they needed to do to manage their diabetes is to reduce their sugar intake (Sowattanagoon, Kotchabhakdi and Petrie, 2009; Ahmad *et al.*, 2014). Furthermore, specific dietary preferences, such as adding sugar, chilli, soya sauce, shrimp paste and salt as the dressing to fruit, are also unique to SEA people and an additional challenge when educating people regarding healthy eating (Sowattanagoon, Kotchabhakdi and Petrie, 2009).

Similarly, there is a high consumption of a particular carbohydrate food among Malaysians. The Malaysian Adults Nutrition Survey reported (N=6,742) that on average, two and a half plates of rice and three teaspoons of sweetened condensed milk in tea or coffee are consumed per day (Norimah *et al.*, 2008). In a prospective study, it was found that high rice consumption is associated with a doubling of the risk of T2DM in Chinese women (Villegas *et al.*, 2007). In a further review, which combined information from multiple sources including: food balance sheets; household expenditure surveys; nutrition surveys; and published studies; it was shown that the consumption of added sugar in Malaysia is those mainly consumed in daily beverages (tea and coffee), which exceeds the 10% of total calories recommended by the WHO in 2015 (Amarra, Khor and Chan, 2016).

Finally, another cultural factor to note is that traditional medicine or complementary and alternative medicine (CAM), are widely used in Malaysia before the introduction of modern medicine, and the latter is still not considered to be the primary and only option among the SEA communities (Ahmad, 2011). A one-year prevalence study in Singapore government primary care clinics found that among 488 randomised adults with chronic disease, 22.7% of the participants practised and used CAM, as it was strongly recommended by family members and therefore, has to be included in their personal diabetes management. Uniquely, the above prevalence study described that its usage is aligned with personal values, religious beliefs and health philosophies, and is not associated with health professional-patient relationship (Lee *et al.*, 2004).

1.5 Management for type 2 diabetes mellitus (T2DM)

Management of T2DM is complex because the disease progresses over time, and that it affects physical and mental wellness. It is recommended that the individual with T2DM should have access to specialist healthcare professionals including physicians, nurses, diabetes educators, dietitians, pharmacists and psychologists. A holistic approach, as well as patient centred care, are essential. It is suggested that an interactive (to allow time for question and answer as well as reflection) and an honest discussion of clinical management guidelines may help support people to self-manage their diabetes and delay the onset of diabetes complications and improve the quality of life for people with T2DM (Zitkus, 2012).

Diabetes management guidelines from the American Diabetes Association (ADA) and the European Association for the Study Diabetes (EASD) 2015, recommend that the management of diabetes should be individualised, and a shared decision-making may empower and motivate people with diabetes towards good self-management (Inzucchi *et al.*, 2012). Optimisation of blood glucose levels is vital. Meanwhile, the International Diabetes Federation (IDF) Global guideline for Type 2 diabetes 2012, (p. 32), recommends ‘that care should be provided to all people with diabetes with respect to their culture and own wishes’ (IDF, 2012).

1.5.1 Non-pharmacological management

Glycaemic control targets

Lifestyle factors, age, genes and family history of diabetes are known to be the main risk factors for the development of T2DM (Chen, Magliano and Zimmet, 2011). Individuals cannot modify their genes or ageing process, but they can modify their lifestyle, such as by increasing physical activity, lose weight, stop smoking and reduce alcohol intake to achieve blood glucose targets and delay complications.

People with diabetes are generally advised to achieve a Glycated haemoglobin (HbA1c) level of below 7.0% of the National Glycohaemoglobin Standardisation Programme (NGSP) units, or 53 mmol/mol of the International Federation of Clinical Chemistry (IFCC) units, to minimise microvascular complications by 25%, as revealed in the landmark trial, the UKPDS, which indicated that a strict glycaemic control is beneficial to reduce disease progression and complications (retinopathy, nephropathy and neuropathy). According to the Ministry of Health Malaysia, the HbA1c target is based on the patients' profile as in Table (1.1).

Table 1.1: The glycated haemoglobin (HbA1c) targets for Malaysians with Type 2 Diabetes Mellitus.

Individualised HbA1c targets and patients' profile		
Tight:		Less tight:
6.0-6.5%	6.6-7.0%	7.1-8.0%
(42-48mmol/mol)	(49-53mmol/mol)	(54-64mmol/mol)
<ul style="list-style-type: none"> Newly diagnosed Younger age No cardiovascular disease complications 	All others	<ul style="list-style-type: none"> Co-morbidities (coronary disease, heart failure, renal failure, liver dysfunction)
Low risk of hypoglycaemia		Prone to hypoglycaemia
Footnote: "modified from the Management of Hyperglycaemia in Type 2 Diabetes: A Patient-Centered Approach A Position Statement of the American Diabetes Association; the European Association for the Study of Diabetes, 2012; The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial, 2008; The Action in Diabetes and Vascular Disease: Preterax, and the Diamicon Modified Release Controlled Evaluation (ADVANCE) trial, 2008"		

Adapted from the Clinical Practice Guidelines: Management of Type 2 Diabetes Mellitus by the (Ministry of Health Malaysia, 2015).

Meanwhile, the fasting or pre-prandial blood glucose level should be in the range of 4.4 to 7.0mmol/L, and the 90-minute post-prandial blood glucose level in the range of 4.4 to 8.5mmol/L. Therefore, glycaemic control (HbA1c % or mmol/mol) should be monitored regularly to aid collaborative care planning. If the blood glucose target is unachievable by lifestyle changes alone, then pharmacological therapy should be initiated.

Dietary advice

Dietary modification targeted towards reducing weight is the main objective in diabetes management, and to ensure sustainability in lifestyle changes, it should consider individual's nutritional needs, personal choices and cultural preferences (NICE Internal Clinical Guidelines Team, 2015). As mentioned in the earlier section,

obesity is one of the major clinical risk factors to develop T2DM and excessive calorie intake in the diet is a contributor to poor glucose control. Research findings suggest that weight loss can help individuals with T2DM in maintaining their glycaemic control, as well as reducing the risk of cardiovascular complications.

Findings from a systematic review and meta-analysis assessing the effects of weight loss intervention among obese people with T2DM demonstrated that intensive weight loss interventions (very low energy diets) are proven to reduce a person's weight by 7% to 10% and significantly reduce fasting plasma glucose by 25% (Anderson, Kendall and Jenkins, 2003). The UK National Institute for Health and Clinical Excellence (NICE) clinical guideline 2015, recommends 5-10% body weight reduction for an overweight adult with T2DM. This recommendation is based on a randomised controlled trial (RCT) data comparing the effect of meal replacement (MR) versus diabetic meal plan on weight loss and glycaemic control, which reported that the MR group had a significantly greater weight reduction ($4.57 \pm 0.81\%$) and a significant improvement (reduction) of HbA1c level by $0.49 \pm 0.22\%$ ($p < 0.05$), compared with the diabetic meal plan group ($2.25 \pm 0.72\%$) (Li *et al.*, 2005).

Meanwhile, an RCT investigating the impact of a combined weight reduction intervention (low-calorie diet, meal replacement products and sibutramine) on weight loss and diabetes control revealed that there was significant weight loss ($-7.3 \pm 1.3\text{kg}$; $p < 0.001$) compared to the standard therapy group ($-0.8 \pm 0.9\text{kg}$), and a weight loss of around 5kg, is associated with at least 0.4% (4 mmol/mol) decrease in HbA1c (Redmon, Raatz and Thomas, 2003). Furthermore, a systematic review and meta-analysis of 20 RCTs to evaluate several types of diets (for 6 months or more) on glycaemic control, lipid level and weight loss demonstrated that low carbohydrate, low glycaemic index (GI), Mediterranean and high protein diets compared to the

control groups are associated with statistically significant reductions in HbA1c level at -0.12% ($p=0.04$), -0.14% ($p = 0.008$), -0.47% ($p = <0.00001$) and -0.28% ($p < 0.00001$) respectively. Greater weight loss was achieved among participants in the low carbohydrate and Mediterranean diet at 1-year follow-up (Ajala, English and Pinkney, 2013).

Physical activity

Physical activity has multiple benefits for individuals with T2DM. It can normalise weight, decrease blood glucose levels and increase insulin sensitivity. It should be introduced gradually to people with T2DM, if they are normally sedentary, to reduce the risk of cardiovascular complications. International guidelines recommend people with T2DM should receive an individualised consultation and set up specific goals to improve their physical activity (IDF, 2012). Findings from a systematic review and meta-analysis of physical activity interventions (N=14; 11 randomised and 3 non-randomised) for adults with T2DM compared with non-exercise control groups demonstrated that in trials where the intervention lasted for more than eight weeks, the HbA1c was significantly lower than that of the control group (7.65% vs 8.31%; weighted mean difference, -0.66%; $p = 0.001$, respectively) (Boule *et al.*, 2001). Most of the included interventions involved aerobic training commonly walking or cycling 3 times per week for 8-15 weeks and resistance exercise training with elastic bands (10 different routine steps with an average of 13 repetitions) at 2.5 times per week for 10 to 15 weeks.

Remission of Type 2 diabetes mellitus

T2DM is known to be a permanent, progressive disease with irreversible beta cell failure. However, recent studies indicate that there is a possibility of T2DM remission (off medication) through weight reduction for individuals with a disease duration of

less than 6 years. However, this is not necessarily possible for everyone with T2DM as it requires extreme lifestyle changes.

The **Diabetes Remission Clinical Trial (DiRECT)** revealed that T2DM could be reversed with intensive weight management (very-low-calorie diet) intervention. It was implemented among obese people with T2DM (N=306) who have not been receiving insulin treatment, with a total diet replacement (formula diet of 825-853 kcal/day) for 3 to 5 months, then following gradual food reintroduction 2 to 8 weeks (50% carbohydrate, 35% total fat and 15% protein), and monthly follow-up visits for weight loss maintenance consultations. The main findings demonstrated that 24% (36 out of 149) of the participants in the intervention group lost around 15 kilogram (kg) or more ($p < 0.0001$) compared with the control group. Almost half (71 out of 149) of the participants in the intervention group reversed the diabetes state measured by HbA1c of less than 6.5% (48 mmol/mol), and were off oral antidiabetic medication after 12 months of intervention, compared to 4% of the control group (odds ratio 19.7; 95% CI 7.8-49.8; $p < 0.0001$) (Lean *et al.*, 2018).

1.5.2 Surgical management of T2DM

In addition to dietary intervention to achieve weight reduction for people with T2DM bariatric surgery may be offered, as a ‘quick fix’ compared with dietary intervention alone, and is especially important as a treatment for people with T2DM who are morbidly obese. Main bariatric surgery can be divided into two types: (i) gastric restrictive procedures (such as gastric banding and vertical gastropasty) and (ii) intestinal bypass surgery (such as Roux-en-Y gastric bypass and biliopancreatic diversion).

The Swedish Obesity Study (SOS) is an on-going prospective study investigating weight loss and glycaemic effect among clinically obese individuals who underwent bariatric surgery (primarily vertical gastropasty) compared with a control group who received conventional obesity treatment over two years. The study demonstrated that 72% of 342 obese patients treated surgically had a successful remission of T2DM, while only 21% of the control group had the same. The surgically treated group significantly reduced their weight by 28 ± 15 kg compared with 0.5 ± 8.9 kg in the control group ($p < 0.0001$) within 2 years of intervention. (Sjostrom *et al.*, 1999). The SOS study reported that the chance of being free from diabetes was higher among the surgically treated group (OR=3.45; 95% CI 1.64-7.28; $p = 0.001$) 10-years post-surgery, and the surgically treated group reduced their baseline weight by 23.4% in 2 years and this was maintained at 16.3% after 10 years (Sjöström *et al.*, 2004).

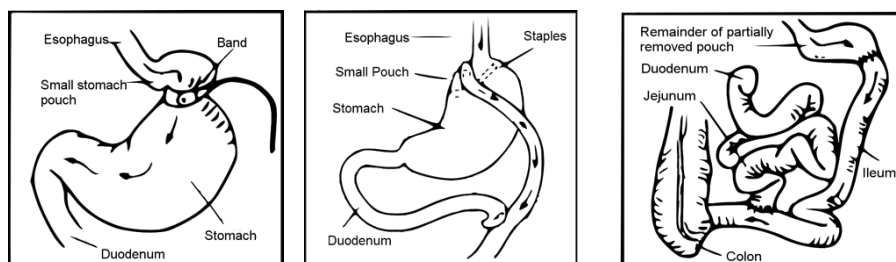
Similar findings were reported in an RCT of 60 participants with T2DM who were clinically obese (BMI range at 30 kg/m^2 to 40 kg/m^2) and randomised to gastric banding surgery or a conventional weight loss programme. Participants in the surgical intervention group succeeded in reducing their weight by 21.1 ± 10.3 kg, compared with 1.5 ± 5.4 kg in the conventional weight loss programme ($p < 0.0001$). 73% of the surgically treated group managed to reverse their diabetic state ($\text{HbA1c} < 6.2\%$, $p < 0.001$) without an antidiabetic agent (Dixon *et al.*, 2008). This effect is mainly due to weight loss facilitating the improvement of insulin sensitivity in the body of people with diabetes as well reducing the burden on the beta-cells following surgery.

The long-term effects of biliopancreatic diversion surgery of 312 people with T2DM indicated that 99% achieved normal fasting glucose level one year post surgery, and 98% of the subjects were still in complete remission from diabetes

(maintained normal blood glucose level without antidiabetic drug) 10 years after the surgery (Scopinaro *et al.*, 2005). Meanwhile, a study by (Schauer *et al.*, 2003), investigating the effect of Roux-en-Y gastric bypass surgery among 1,160 individuals who were morbidly obese of whom 21% had a diagnosis of diabetes, demonstrated a significantly improved metabolic control (HbA1c returned to normal level) among most (83%) of the participants diagnosed with diabetes. Both Roux-en-Y gastric bypass and Bilio-pancreatic diversion procedures have an effect on gut hormones (increases of Glucagon-like-peptide 1 (GLP-1)) that assist the reversal of obesity and hyperglycaemia. The GLP-1 reduces glucagon secretion post-prandially, which slows gastric emptying and reduces post-prandial glucose level due to delays in digestion as well as promoting satiety.

Table (1.2) summarises the surgical procedure and the outcomes which assist in remission of diabetes. In conclusion, the clinical manifestation and glycaemic control of T2DM are resolved or improved when individuals successfully modify their lifestyle, through dietary behaviour, physical activity and weight loss (non-pharmacological management). Therefore, diabetes health professionals involved in diabetes care should be a source of continuous encouragement and guidance, to support their patients in making these lifestyle changes.

Table 1.2: Summary of common bariatric surgery and the outcomes of each procedure.



Type of surgery overview	Laparoscopic gastric banding	Roux-en-Y gastric Bypass	Bilio-pancreatic diversion
Surgery overview	The less invasive procedure where patients have a smaller stomach pouch that leads to reduced food intake.	A bypass stomach pouch is made and connected to the ileum either at the alimentary or the digestive limb. As a result, the mixing process of biliopancreatic secretions and nutrients occurs in the ileum and shortens the absorption process.	A partial gastrectomy with a duodenal stump is made, while the remaining gastric pouch is connected to the final segment of the small intestine (bypassing the upper part of the small intestine). Most calories goes straight to the colon, and a lesser absorption leads to weight loss.
Excess weight loss	46.2%	59.5%	63.3%
Remission of T2DM	Slow	Rapid	Rapid
Insulin sensitivity	Improved	Improved	Greatly improved
Glucagon-like-Peptide 1 (GLP-1)	No-change	Increased	Increased

Adapted and modified from (Kashyap *et al.*, 2010), with data summarised from (Buchwald *et al.*, 2009).

Images from Wikimedia, licensed for unrestricted use in the public domain, accessed 2nd January 2019. This image is a work of the National Institutes of Health, part of the United States Department of Health and Human Services. As a work of the U.S. federal government, the image is in the public domain.

1.5.2 Pharmacological management

Lifestyle modification such as dietary management, physical activity and weight reduction is the cornerstone of T2DM management. However, as T2DM progresses pharmacological (oral and/or injectable) treatment is usually required to help people with T2DM to achieve their glycaemic target. Table 1.3 illustrates the NICE guideline of recommendations for treatment for people with T2DM, who are unable to achieve blood glucose level targets through lifestyle intervention alone. Generally, the response to prescribed medication should be monitored, taking into consideration tolerability and hypoglycaemia, in which ineffective therapies should be changed to alternative options or to be discontinued.

Most guidelines suggest that glycaemic target should be specific to an individual with T2DM. However, it should achieve as near to normal glycaemia as possible without causing hypoglycaemic event. Table 1.4 presents the recommended treatment regime for people newly diagnosed with T2DM according to the clinical guidelines of the Ministry of Health Malaysia.

Table 1.3: Treatment regime if blood glucose targets are not achieved through lifestyle by The National Institute for Health and Clinical Excellence (NICE), UK.

If HbA1c rises to 48 mmol/mol (6.5%) on lifestyle intervention	<ul style="list-style-type: none"> • To prescribe standard release metformin and change to modified release if not tolerated. • Monitor renal function, use with caution if eGFR <45 ml/min/1.73 m². • HbA1c target = 48mmol/mol (6.5%) • If metformin contraindicated or not tolerated to consider: <ul style="list-style-type: none"> - a DPP-4i, pioglitazone or an SU <ul style="list-style-type: none"> - an SGLT-2i instead if a DPP-4i , an SU or pioglitazone is not appropriate - supportive measure to achieve HbA1c at 48 mmol/mol (6.5%) for people on a DPP-4i, SGLT-2i or pioglitazone or 53 mmol/mol (7.0%) for people on an SU.
<i>When glucose targets are not achieved</i>	
First Intensification: If HbA1c rises to 58mmol/mol (7.5%)	<ul style="list-style-type: none"> • To consider for dual therapy as below: <ul style="list-style-type: none"> - metformin + DPP-4i - metformin + pioglitazone - metformin + an SU - metformin + an SGLT-2i • Supportive measures to achieve the HbA1c target at 53 mmol/mol (7.0%). • If metformin contraindicated or not tolerated to consider: <ul style="list-style-type: none"> - a DPP-4i and pioglitazone - a DPP-4i and an SU - pioglitazone and an SU - supportive measure to achieve HbA1c at 53 mmol/mol (7.0 %).
<i>When glucose targets are no longer being achieved</i>	
Second Intensification: If HbA1c rises to 58 mmol/mol (7.5%)	<ul style="list-style-type: none"> • Insulin programme <u>or</u> to consider triple therapy as below: <ul style="list-style-type: none"> - metformin + a DPP-4i and an SU - metformin + pioglitazone and an SU - metformin + pioglitazone and an SU or an SGLT-2i • Supportive measures to achieve the HbA1c target at 53 mmol/mol (7.0%) • If metformin contraindicated or not tolerated to consider insulin-based treatment.
<i>Insulin-based treatment</i>	
<ul style="list-style-type: none"> • To continue with metformin if no contraindications or if there is intolerance. Review the continued need for other blood-glucose-lowering therapies. • To prescribe NPH insulin once or twice daily according to need • If HbA1c is 75mmol/mol (9.0%) or higher to consider both NPH and short-acting insulin either separately or as pre-mixed (biphasic) human insulin. • To consider insulin detemir or Glargine if the person needs assistance to inject OR facing hypoglycaemic episodes OR need twice-daily NPH insulin in combination with oral blood glucose-lowering drugs. • If the person prefers injecting before meals OR blood glucose rises markedly before meal OR facing hypoglycemic episodes to consider short-acting insulin analogues. • Monitor people on insulin for the need to change the regime 	
Abbreviations: DPP-4i Dipeptidyl peptidase-4 inhibitor, GLP-1 glucagon-like peptide-1, SGLT-2i Sodium-glucose cotransporter 2 inhibitors, SU Sulfonylurea, NPH neutral Protamine Hagedorn (an intermediate-acting insulin).	

Adapted and summarised from Type 2 diabetes in adults: Management, Clinical guideline update (NG28), Methods, evidence and recommendations (NICE Internal Clinical Guidelines Team, 2015).

Table 1.4: Treatment regime for people newly diagnosed with Type 2 Diabetes Mellitus by the Ministry of Health Malaysia.

Diagnosis of Type 2 Diabetes				
Lifestyle Modifications				
A1c < 6.5% FPG < 6 mmol/L	A1c 6.5% - < 7.5% OR FPG 6-< 8 mmol/L	A1c 7.5% - < 8.5% OR FPG 8-<10mmol/L	A1c 8.5% - 10% OR FPG 10-13 mmol/L	A1c > 10% OR FPG > 13mmol/L
LIFESTYLE APPROACH	OAD MONOTHERAPY	DUAL COMBINATION THERAPY	TRIPLE COMBINATION THERAPY	Combination therapy + Basal / Premixed Insulin Therapy
If postprandial is >11.0 mmol/L consider one of the following:	Metformin OR any one of below:	Any two combinations of below:	Any three combinations of below:	OR Intensive Insulin Therapy + OAD
Metformin	SU	Metformin	Metformin	
Glinides	Glinides	SU	SU	
AGI	AGI	Glinides	Glinides	
DPP-4i	TZD	AGI	AGI	
	DPP-4i	TZD	TZD	
	GLP-1 RA SGLT-2i	DPP-4i GLP-1 RA SGLT-2i Insulin	DPP-4i GLP-1 RA SGLT-2i Insulin	
Follow-up with A1c after 3 months	Optimise dose of OAD agent in the subsequent 3 months Follow-up with A1c after 3 months	Optimise dose of OAD agent in the subsequent 3 months Follow-up with A1c after 3 months	Optimise dose of OAD agent in the subsequent 3 months Follow-up with A1c after 3 months	
If A1c ≤ 6.5% continue with the lifestyle approach.	If A1c ≤ 6.5% continue therapy	If A1c ≤ 6.5% continue therapy	If A1c ≤ 6.5% continue therapy	

Abbreviations: *DPP-4i* Dipeptidyl peptidase-4 inhibitor, *GLP-1 RA* glucagon-like peptide-1 receptor agonists, *SGLT-2i* Sodium-glucose cotransporter 2 inhibitors, *SU* Sulfonylurea, *AGI* α-glucosidase inhibitor, *TZD* thiazolidinediones, *A1c* Glycated haemoglobin, *OAD* Oral anti-diabetic

Footnote:

Metformin	Efficacious, low risk of hypoglycaemia & weight neutral
SU, Glinides, Insulin	Efficacious, high risk of hypoglycaemia and weight gain
DPP-4i	Moderate efficacy, low risk of hypoglycaemia & weight neutral
GLP-1 RA, SGLT-2i	Moderate efficacy, low risk of hypoglycaemia and weight loss
TZD (Pioglitazone)	Moderate efficacy, low risk of hypoglycaemia and weight gain
AGI (Acarbose)	Moderate efficacy, low risk of hypoglycaemia and weight neutral

Adapted and modified from the Clinical Practice Guidelines: Management of Type 2 Diabetes Mellitus by the (Ministry of Health Malaysia, 2015).

1.5.3 Diabetes Self-management

Self-management is a term mainly used in behavioural change interventions or programmes and health promotion, especially for the management of chronic conditions, where there is evidence of the effectiveness of self-management interventions (Lorig and Holman, 2003). People with T2DM need to self-manage their diabetes, and healthcare professionals in addition to providing medical management and monitoring, are also a resource to provide education regarding diabetes and management to close the knowledge and skills gap and support their patients.

In the 1990s, (Von Korff *et al.*, 1997) coined the term ‘collaborative management’ where patient and healthcare professionals share the same goal, work as a team and play their respective roles effectively. Barlow *et al.* (2002, p.178) defined self-management as an ‘individual's ability to manage the symptoms, treatment, physical, psychosocial and lifestyle changes inherent in living with a chronic condition’ (Barlow *et al.*, 2002). Self-management among people with T2DM can be enhanced if they have the information and skills included as part of their treatment plan, including management of emotional impact, to ensure they are able to manage their disease on a day-to-day basis.

To summarise, the most significant challenge faced by people with T2DM and healthcare professionals is optimising glycaemic control, managing cardiovascular risk factors and quality of life through lifestyle modification and pharmacological treatment when indicated. For this reason, ongoing support through effective diabetes self-management education (DSME), which could provide the knowledge, skills and support required, may overcome barriers to self-management, improve quality of life and delay complications for people diagnosed with T2DM.

1.6 Diabetes self-management education (DSME)

People with diabetes spend limited time with their healthcare professionals whereas they need to make their own daily decisions that may affect their diabetes management, long-term health and quality of life.

A systematic review and meta-analysis of randomised controlled trials (RCTs) assessing group based DSME compared with usual care demonstrated decreased glycaemic control (HbA1c) at 6 months, 12 months and 2 years by 0.44%, 0.46% and 0.87% respectively ($p < 0.001$), as well as an improved diabetes knowledge (effect size (ES) = 0.83), self-efficacy (ES= 0.28) and self-management skills (ES= 0.55) 6 months post intervention (Steinsbekk *et al.*, 2012).

The American Association of Diabetes Educators (AADE) defines diabetes self-management education (DSME) as: ‘The ongoing process of facilitating the knowledge, skill, and ability necessary for prediabetes and diabetes self-care’ (Haas *et al.*, 2012, p. 2). The AADE recommends a patient-centred approach to DSME to change behaviour and achieve seven specific self-care behaviours: healthy eating; being active; monitoring; taking medication; problem-solving; healthy coping; and reducing risks.

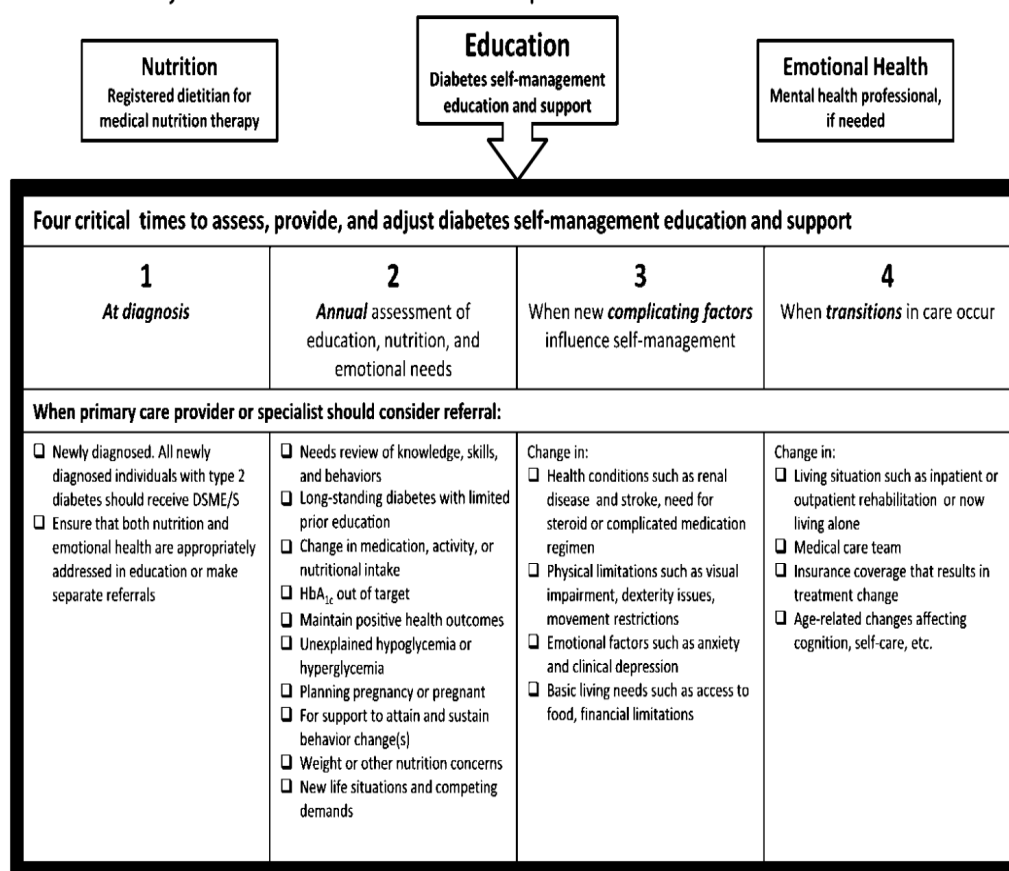
According to the ADA, the AADE and the Academy of Nutrition and Dietetics, there are four critical points at which support should be provided through DSME, namely; 1) at diagnosis; 2) annual support for maintenance and delaying complications; 3) after one complication occurs; and 4) as transitions of care are initiated (Powers *et al.*, 2015). Figure 9 provides details of the DSME algorithm of care by the ADA.

Taking into consideration recommendations at diagnosis by the ADA, the intervention study described in this PhD thesis was explicitly developed for Malaysians newly diagnosed with T2DM, because at this point, it is so crucial for them to develop self-efficacy and build their motivation for better self-management.

Figure 9: Diabetes Self-Management Education (DSME) algorithm of care by the American Diabetes Association (ADA).

Diabetes Self-management Education and Support for Adults With Type 2 Diabetes: Algorithm of Care

ADA Standards of Medical Care in Diabetes recommends all patients be assessed and referred for:



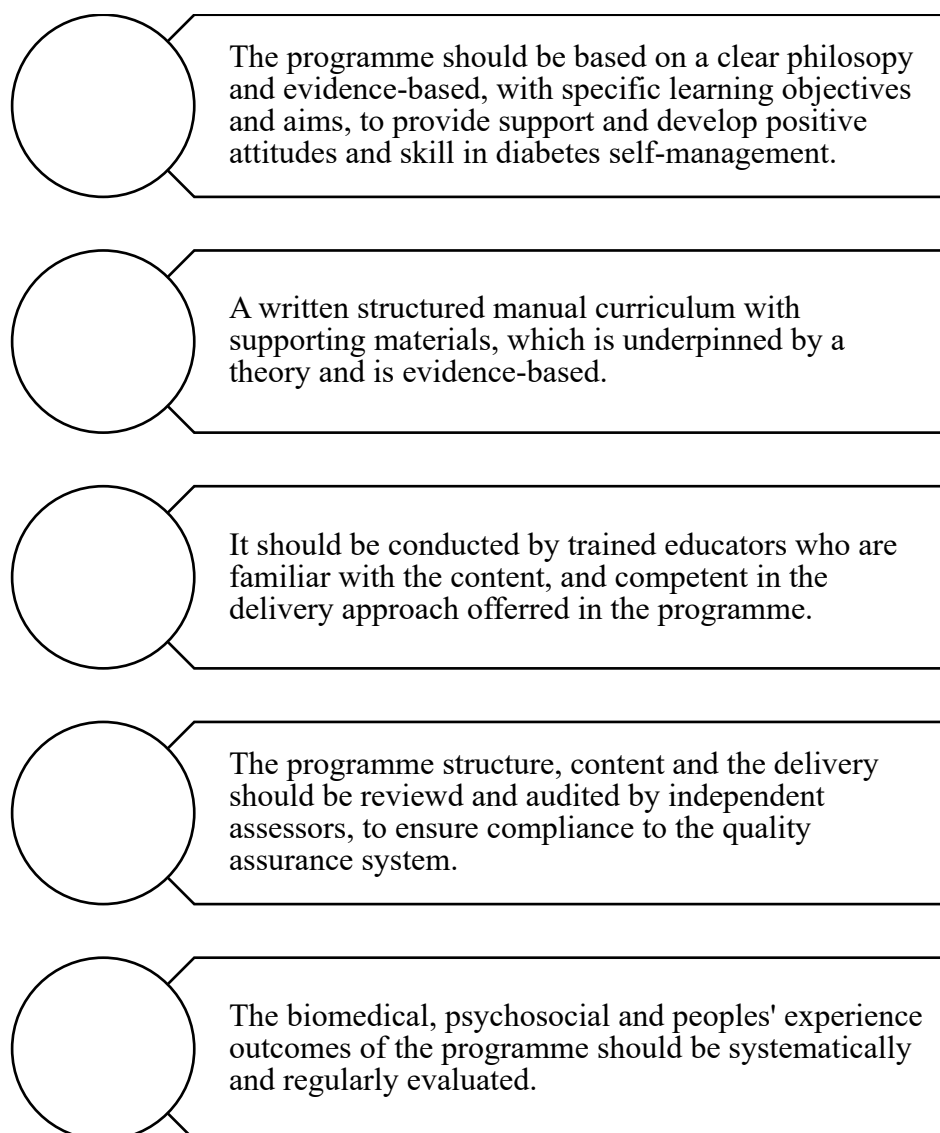
Adapted from the Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association , the American Association of Diabetes Educators , and the Academy of Nutrition and Dietetics (Powers *et al.*, 2015).

In the UK, the term ‘structured diabetes education (SDE)’ is widely used. However, there are differences between DSME and SDE and these will be discussed in the following section.

1.6.1 What is structured diabetes education (SDE)?

Generally, SDE is a diabetes educational course that is implemented and conducted by healthcare professionals, usually a diabetes specialist nurse or dietitian, to provide detailed information on managing diabetes through diet, physical activity and medication. The Institute for Health and Clinical Excellence (NICE) Health Technology Appraisal (HTA) 2003 defined structured education as ‘a planned and graded programme that is comprehensive in scope, flexible in content, responsive to an individual’s clinical and psychological needs, and adaptable to his or her educational and cultural background’ (National Institute for Health and Clinical Excellence, 2003). This definition recommends that any diabetes educational intervention should be able to provide knowledge, improve skills and be tailored to achieve specific needs and cultural requirements to assist people in adopting and maintaining lifestyle modifications. Furthermore, it is recommended that structured and annually accredited education programmes should be offered to people with diabetes and their carer. The key characteristics endorsed by NICE (NICE Internal Clinical Guidelines Team, 2015) in producing a high-quality structured education that may prepare people for their lifetime management with the condition are shown in Figure 10.

Figure 10: Key characteristics of a diabetes structured education programme by NICE 2015.



The **d**iabetes education and self-management for **o**ngoing and **n**ewly diagnosed (DESMOND) and the ‘**E**xpert education versus **r**outine **t**reatment’ (X-PERT) in the UK are good examples of evidence-based SDE programmes for type 2 diabetes that meet the criteria set by NICE. The DESMOND programme enhances self-management by educating people with T2DM to understand their illness, giving them practical skills in self-care and providing them with techniques to sustain their motivation in their life-long self-management through a 6-hour group-based approach, either as a one day or two half-day session/s by two facilitators. The landmark DESMOND multi-site RCT (N= 1109) demonstrated significant weight reduction and smoking cessation among participants at 12-months follow-up (Davies *et al.*, 2008).

Another known diabetes structured education programme is the ‘**E**xpert education versus **r**outine **t**reatment’ (X-PERT) diabetes programme for T2DM available in the UK. The programme uses a group-based approach with 6 weekly sessions (2.5 hours per session) delivered by trained educators who are health professionals, and its effectiveness at improving glycaemic control was demonstrated in a single-centre RCT (Deakin *et al.*, 2006).

Alternative options should be offered to those who are unable to attend any face-to-face structured diabetes education, because it is crucial to meet their needs and promote good self-management. Virtual educational interventions or web-based approaches are examples which allow people with diabetes to access information and an innovative way for health professionals to reach out to this particular group. For example, the **H**ealthy **L**iving for **P**eople with Diabetes (HeLP-Diabetes) is an Internet-based self-management tool aimed to support people with diabetes in terms of emotional, medical as well self-role management, which demonstrated a significant improvement in glycaemic control in the intervention group, as compared with the

usual care control group. The mean difference in HbA1c was reduced by -0.24% (95% CI -0.44 to -0.049; $p = 0.014$) after 12-months of intervention (Murray *et al.*, 2017).

Considering the global costs of treating and managing diabetes and its complications is 825 billion USD a year with China spending the most (170 billion USD), followed by the US (105 billion USD), and India as the third (73 billion USD), there is an urgent need to support people with diabetes to avoid long-term problems associated with their condition. Therefore, the efficacy and cost-effectiveness of diabetes treatment and DSME is in the spotlight. A cost-effectiveness analysis study of the DESMOND intervention concluded that not only were there positive results for people with T2DM who received the intervention (such as weight reduction and smoking cessation), but the DESMOND was also likely to be economically useful compared with the usual care at the primary care level (Gillett *et al.*, 2010).

In conclusion, the main objective of diabetes structured education for people with T2DM is to provide information regarding the disease process, prepare people with skills to self-manage and provide motivational support to give them the confidence to effectively self-manage their diabetes. In Malaysia, however, there is currently no structured education for people with T2DM (for further information please see Chapter 4) and the main aim of this thesis is to develop a new programme of education for people with a new diagnosis of T2DM. This process of development involves qualitative research and the next section discusses the role of the researcher in this process as it has an impact on the trustworthiness of the data and knowledge arising from this thesis.

1.7 Reflexivity statement

The role of a researcher as data collection tool in research needs some considerations to confirm the integrity of a particular study, due to the researcher invariably bringing their values, beliefs, assumptions, professional background and interest during the research process. These personal values and professional experiences may give an impact on the findings of the current study as suggested by (Finlay & Gough 2008). Therefore, to reduce personal and intellectual biases the researcher needs to explicitly detail their value, assumptions and own motivation at each stage of the study process.

This thorough, thoughtful and transparent self-reflection activity is known as the reflexivity or positionality statement and can be defined as “the constant movement between being in the phenomenon and stepping outside of it” (Enosh & Ben-ari, 2016, p. 578). As recommended by (Hewitt, 2007; Mays & Pope, 2000), the reflexivity process is to confirm that the researcher is sensitively and consciously aware of how the above factors might shape the data and the findings of the study. Apart from that, it reveals the personal and professional experience and its contribution in understanding the participants' input, and at the same time provide some insights to the reader while exploring the research outcomes.

This section describes how the researcher applied the reflexive process to gain the insights and evaluate how this affected the process and findings of the study, and how it may change the researcher's perspective. Overall, this PhD thesis project is a challenging and an enjoyable learning experience. The researcher has divided the reflection of this research journey into the following three stages, as recommended by (Finlay, 2002) namely; (1) Pre-research; (2) data collection, and (3) data analysis.

1.7.1 Pre-research stage

At the beginning of this research, the researcher reflected explicitly on both her personal and professional experiences within this topic. The researcher examined the motivations, assumptions and interest in this particular topic to recognise how it would direct or skewed the research process.

The interest in the DSME evolved from the researcher's personal experience. Out of 18 of her uncles and aunties from both maternal and paternal sides, only three were not-diagnosed with T2DM. A total of six died due to complications such as heart diseases, sepsis and kidney failure while the remaining were either newly diagnosed or diagnosed with complications. However, the researcher observed the pattern of premature mortality among them mainly happened to those with family problems and kept complaining of having difficulties in controlling their blood glucose level even though optimum care was taken for their diet, physical activity and adherence to their medications.

Coincidentally, at that particular time, the researcher was looking at topics for her PhD programme. Through reading scientific articles, the researcher found that there is an association between mental health problems and diabetes control. Reading this evidence made the researcher reflect on her professional experience as a nurse and academic trainee, who also acted as a clinical supervisor at primary care clinics. While in the clinical setting, the researcher noted of the limited education sessions for people with T2DM to support their self-management. This also strengthens this hypothesis because the researcher acts as a primary reference or resource person in the family, regarding their T2DM and how to manage them at home. Following several sessions

of self-reflection, the researcher identified a gap in Malaysian healthcare setting, in the form of ineffective communication or approach during any consultation, for people with T2DM.

The researcher noticed that there were limited access and mental health support given to people with T2DM in clinical practice. The researcher also learned through her role as the primary point of contact for patients and family, limited information is gained during their clinical visits. At this point, the researcher started to question why this is happening. The researcher wondered what happen to others with T2DM who do not have anyone to rely on among their family members. Were they able to gain reliable information and resources to support their self-management, or end-up taking advice from unqualified individuals, or from unreliable websites?

Therefore, to gain an understanding of the need for an effective diabetes self-management, one of the phases that was conducted in this study is the qualitative synthesis. The findings are presented in Chapter 3. This study thus sought to contribute to the body of knowledge and inform the development of the DSME intervention phase for Malaysian with T2DM, and is found to be achievable among Malaysian adults who were recently diagnosed with T2DM.

1.7.2 Data collection stage

At the beginning of the participants recruitment, the researcher introduced herself as a researcher from King's College London and a former academic from the International Islamic University Malaysia. Nonetheless, while interacting (during interviews or implementation of the intervention) with the participants throughout the study, disclosure of her professional status (as a nurse) occurred. The researcher

however emphasised her interest currently lies in research, specifically to develop a culturally acceptable diabetes education to assist Malaysians with T2DM. When disclosure occurred, the researcher felt that they were more likely to be open for discussion, and expressed their gratitude for the opportunity to speak to a health professional, and felt that they were in good hands. Without a nurse uniform, they (the participants) openly discussed both positive and negative views of their experiences relating to diabetes self-management. However, it was noted that although they were given the assurance that any parts of this research activities would not affect the care that they are received at the primary care clinics, some of the participants still appeared hesitant to share their negative feedback.

Despite, the researcher's position as a researcher, there were situations where conflict occurred between the two roles held, the researcher and the nurse (clinical role). For example, a gentleman complained of having the side effects of an oral anti-diabetic medication and expected a consultation from the researcher. At the end of the interview, the researcher reiterated her current non-clinical role and advised the gentleman to contact the clinic that provides his routine follow-up care. The researcher clarified the usual protocol with the nurse-in-charge in the clinic, and she confirmed that patients can always seek advice outside of their routine follow-up appointments, and a pharmacist is also available to discuss queries regarding their medications, and they will refer to the physician if needed. What the researcher has learned from this is that, as a researcher we should be able to step-back from formally providing any clinical advice and interfere in their planned care.

With a majority of family members with T2DM, this has put her in a unique position with inside knowledge while interviewing, and during the implementation of the intervention. Therefore, she felt that she was able to understand their feelings and struggle, as well as display some level of empathy. However, the researcher had to guard herself against assuming that her experiences may help them in their diabetes management and continuously reflect that each person with T2DM would have different experiences. Despite the advantages of being an ‘insider’, the researcher channelled the experiences through an open, active discussion and sharing moment sessions during the intervention. It was also a great opportunity learning from these participants.

Field notes were written at the end of each interview. It contains participants’ non-verbal cues and their story (narratives), in as much detail as possible, which also included the researcher’s own insights. For instance, facial expression of the participants while sharing their feelings of being diagnosed with T2DM were recorded. Thus, with this practice, the researcher hopes to support the reliability of this study.

1.7.3 Data analysis stage

The researcher is aware that some of the personal experiences and assumptions seemed to be challenged during the period of data collection, and this was portrayed during the data analysis. For example, initially, the researcher focused on the psychological factors and ineffective communication and approach by health professionals, but the participants put more emphasis on cultural, social and environmental barriers during the qualitative interviews.

Meanwhile, the reflexive notes that recorded the researcher's thoughts during the data collection period were referred to throughout the data analysis process, which may reduce the intellectual bias in the interpretation of participants' narrative during the theme development. Moreover, the conclusion of the themes was made after a few discussions between the researcher and her PhD supervisor.

In a nutshell, it is not always possible for social science researchers to be fair in their thoughts and feelings, and to reduce their preconceptions, but some efforts were made by the researcher in ensuring that they were recorded (assumptions) throughout the research process. The researcher was able to ensure self-awareness and reduced personal reactions throughout this reflexive process, to improve the credibility and accuracy of the findings. The researcher believes her personal and professional experiences have boosted her passion for research, rather than inappropriately influencing the analysis of the recent data collected.

1.8 Summary

People with T2DM have greater mortality, morbidity and poor quality of life. The increased cost of T2DM treatment is particularly draining on the Malaysian health service as well as for individuals. T2DM complications may be delayed when both medical and self-management can be optimised. Educational interventions may increase self-efficacy, support self-management and improve glycaemic control. However, there are none currently available for people newly diagnosed with T2DM in Malaysia. In order to develop a new education programme, it was necessary to discuss here the role of the researcher throughout the research process.

This chapter summarised the pathophysiology and risk factors of T2DM and its management as well as the role of DSME. The following chapter will discuss the systematic review conducted to synthesise the evidence for DSME in the Asian Western Pacific region to inform the development of a culturally tailored Malaysian diabetes education intervention using motivational interviewing (MY DEUMI) for people newly diagnosed with T2DM, which is the main aim of the research project for this thesis.

Chapter 2 : A Systematic Review of Diabetes Self-Management Interventions for People with Type 2 Diabetes Mellitus in the Asian Western Pacific Region.

2.1 Chapter scope

This chapter presents a systematic review of DSME Interventions for People with T2DM in the Asian Western Pacific (AWP) Region, which have been submitted for publication. This chapter consists of 4 main sections. The first section explains the background and aims of the systematic review. The second section describes the systematic review method. This is followed by a narrative synthesis of the studies included. Finally, the findings are discussed, followed by the strengths, limitations and practical implications for future research, and the way they relate to the next phase of the thesis.

2.2 Introduction

Around 387 million people live with diabetes worldwide and T2DM is the most common comprising 90% of those with diabetes (American Diabetes Association, 2004). Furthermore, 138 million people with T2DM live in the Asian Western Pacific (AWP) region representing 30% of the total number of people with diabetes around the world (a prevalence of 8.5%) (International Diabetes Federation, 2013). The AWP region is vast both in population and geographical size (Figure 11). The region encompasses East Asia (China, Japan, Republic of Korea), Southeast Asia (SEA) (Indonesia, Malaysia, Singapore, Brunei, Thailand, Myanmar, Laos, Cambodia, Vietnam, Philippines) and Oceania the collective name for the islands scattered throughout most of the Pacific Ocean (Australia, New Zealand and French Polynesia in the East) and is diverse in terms of ethnicity, politics, economy and health system, resources, cultural and religious beliefs.

Diabetes Self-management Education (DSME) provides information and skills needed by people with T2DM to effectively self-manage their diabetes in addition to medical management to achieve optimal glycaemic control (Funnell and Anderson, 2004). Developed countries such as the United Kingdom (UK) and the United States of America (USA) have successfully integrated DSME or structured diabetes education into their health systems, both with national guidelines for DSME provision (Haas *et al.*, 2012; NICE Internal Clinical Guidelines Team, 2015).

Figure 11: Map showing the countries and regions of Asian Western Pacific.



Adapted from (WHO Regional Office of Western Pacific, 2009).

In the USA, a DSME is designed by the guiding principles, namely: (i) Effective for improving clinical outcomes and quality of life; (ii) Evolves from theoretically based empowerment models; (iii) Improved outcomes through culturally and age-appropriate programs incorporating behavioural and psychosocial strategies, bearing in mind that there is no “best” education approach; (iv) Ongoing support which is critical to sustaining progress and; (iv) Behavioural goal-setting as an effective strategy (Powers *et al.*, 2015).

Meanwhile in the UK, the DESMOND programme is an effective interactive and collaborative group structured education designed for people newly diagnosed with T2DM, in which improved clinical outcomes were demonstrated in the

randomised trial (Davies *et al.*, 2008). Another example from Latin America, is the **Diabetes Self-Management Program (DSMP)**, which was developed by the Stanford Patient Research Education Centre. A randomised trial of the DSMP group intervention was conducted in community settings (churches, libraries and hospital), through which improvement were shown in self-reported depression, healthy eating habits and self-efficacy (Lorig *et al.*, 2009).

Both of these programmes have now been rolled out, highlighting that translational research benefits people in the community through new policy or evidence-based services. The National Institutes of Health (NIH), define translational research as including, ‘...the process of applying discoveries generated during research ...and ...the adoption of best practices in the community’ (National Institutes of Health, 2009). Patient-oriented research such as DSME are translational and demonstrate effectiveness. Therefore, it is important to look at the AWP region to see what has been implemented previously, and to determine potential barriers. Other systematic reviews of diabetes education or DSME are not focused on the AWP region but rather, on particular populations.

A systematic review and meta-analysis of 53 RCTs of diabetes education specifically among adult Chinese has demonstrated improvement in the HbA1c level and a better glycaemic control, though the interventions were of short duration (30 to 150 minutes per session). The findings of this review support a didactic teaching approach for Chinese adults perhaps for cultural reasons, and this is at odds with the shift towards patient centred and active participation facilitated teaching in the Western countries (Choi *et al.*, 2016). Additionally, a meta-analysis of 12 culturally tailored diabetes education RCTs among ethnic minorities (African Americans, Hispanic American, South Asians in the Europe and the UK and Canadian Portuguese)

with T2DM demonstrated that participants benefited from the intervention, where the effect size for the reduction in HbA1c was -0.41 (95% CI, -0.61 to -0.21), with the majority 84% (n=12) of the studies were group based or a combination of group and individual counselling. This study did not include many people of Asian origin, as the majority of the included studies were of African or Hispanic American populations (Nam *et al.*, 2012).

Meanwhile, findings from a systematic review of RCTs revealed that trials conducted in South Asian countries had a greater significant reduction of HbA1c (4 out of 5 studies, $p < 0.001$), compared to the trials in the Western countries (only 1 out of 4 studies, $p < 0.001$). The study concluded that deep structured cultural adaptations where sociocultural value, historical context and specific psychological factors, which are well integrated for indigenous people, has resulted in a greater impact on glycaemic control compared with the trials implemented in the Western countries on immigrant populations, which were only superficially culturally tailored (language, location and food) (Bhurji *et al.*, 2016).

The International Diabetes Federation (IDF) global diabetes scorecard reported in 2014 that less than 1% of the countries in the AWP region integrate DSME in their health services (International Diabetes Federation, 2014), which suggests that the AWP countries are behind most of the western developed countries when it comes to supporting patients with diabetes self-management. There is a need for DSME in the AWP region, where interventions are being developed and tested, and therefore, focusing on a systematic review of DSME research in the AWP region may give a better understanding of which approaches are associated with better clinical outcomes.

2.3 Aims of the study

The main objective of this review is to synthesise the evidence for DSME interventions employing educational and/or psychological interventions for people with T2DM in the AWP region, and to determine whether culturally specific techniques or sessions were incorporated as part of the program. Second, to summarise the main findings of the included studies. Third, to determine whether the evidence could inform the development of the intervention tested in this (MY DEUMI) project, particularly in tailoring a DSME to the diverse Malaysian community. Below are the research questions which the systematic review sought to answer:

1. Is diabetes education or DSME more effective than the usual care in optimising glycaemic control among people with T2DM?
2. What is the diabetes education or DSME approach that may help people with T2DM to achieve the optimum blood glucose level?
3. Is culturally tailored diabetes education or DSME effective in the AWP region?

2.4 Methods

2.4.1 Search strategy

Following the Preferred Reporting Items for Systematic Review (PRISMA) guidelines, eligible studies were identified from MEDLINE and EMBASE using the Ovid platform; CINAHL in the EBSCOhost platform; PubMed; as well as the Web of Science and ASSIA from the Proquest platform. The search was carried out using the PICO (P: Patient or problems; I: Intervention being considered; C: Comparison intervention; O: Outcome measurements) framework (Davies 2011), and were performed on 7th August 2015 (updated on 16th August 2015 and 21st June 2018). Table (2.1) demonstrates the example of search strategy and keywords used ('type 2 diabetes mellitus' or 'non-insulin dependent diabetes mellitus' or 'diabetes mellitus' AND 'health education' or 'diabetes education' or 'diabetes self-management' or 'behaviour therapy' or 'psychological intervention' or 'psychotherapy' AND 'Asian Western Pacific' countries) during the search. Exploded keywords and MESH terms for MEDline were included, with modified truncation according to different search platforms.

Table 2.1: Detailed search strategies for the systematic review of Diabetes Self-Management Education (DSME) interventions for People with Type 2 Diabetes Mellitus (T2DM) in the Asian Western Pacific (AWP) region. This search strategy was developed for EMBASE and modified to correspond the terminology for other databases.

Search	String
1	Type 2 diabetes mellitus.mp. or exp non-insulin dependent diabetes mellitus
2	Diabetes mellitus.mp. or exp diabetes mellitus/
3	#1 OR #2
	Interventions Terms
4	Health education.mp. or health education/
5	Diabetes education.mp. or exp diabetes education/ or exp patient education/ or exp self-care/
6	Diabetes self-management.mp.
7	Exp behaviour therapy/ or behv\$ therapy.mp.
8	behav\$ intervention.mp.
9	psych\$ intervention.mp.
10	Exp psychotherapy/ or psych\$ therapy.mp.
11	#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10
12	(American Samoa or Australia or Brunei Darussalam or Cambodia or China or Cook Islands or Fiji or French Polynesia or Guam or Hong Kong or Japan or Kiribati or Macao or Malaysia or New Caledonia or New Zealand or Niue or Northern Mariana Islands or Palau or Papua New Guinea or Philippines or Republic of Korea or Samoa or Singapore or Solomon Islands or Thailand or Tonga or Tuvalu or Marshall Islands or Micronesia or Mongolia or Nauru or Vietnam or Vanuatu or Wallis) .mp. [mp=abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
13	#3 AND #11 AND 12

2.4.2 Selection criteria

This systematic review also included comparative studies. This is defined as randomised controlled trials (RCTs); non-RCTs; observational studies using a comparison group and only face-to-face DSME delivery. The broad inclusion criteria ensured all studies measuring the effectiveness of DSME in adults aged 18 and over with T2DM in different healthcare settings were included. Search results were assessed using either the abstract and/or the full text, to determine whether they met the inclusion criteria. No limit was made on the language of publication. Eligible papers that were written in a different language were translated. Studies in which the participants were diagnosed with type 1 diabetes mellitus (T1DM), gestational diabetes and a mixture of T2DM with T1DM or other chronic conditions, were excluded. Apart from that, studies solely investigating pharmacological or medication adherence, diet, exercise, physical activity, web-based or peer support or telephone counselling were also excluded to reduce confounding bias.

The AADE define a DSME as ‘the ongoing process of facilitating the knowledge, skill, and ability necessary for prediabetes and diabetes self-care’ (Haas *et al.*, 2012, p. 620). DSME interventions employ a patient-centred approach as it helps people with T2DM to change their behaviour and achieve seven specific self-care behaviours: healthy eating, being active, monitoring, taking medication, problem-solving, healthy coping and reducing risks. DSME interventions were classified into being: (i) predominantly educational interventions; or (ii) predominantly psychological interventions.

Educational interventions were defined as those that provide information on diabetes, its causes and management (medications or self-management) (Verkuijlen *et al.*, 2014), and may include didactic as well as facilitative teaching approaches. Didactic teaching is a traditional lecture-based teaching methodology that is teacher-centred, while facilitative teaching refers to being a learner-centred approach and is more flexible, combining teaching methodology with practical sessions such as exercise classes and telephone follow-ups (Prince and Felder, 2006). In addition, the facilitative teaching approach may be underpinned by behavioural theories (Jackson, 1997; Anderson and Funnell, 2008), such as: the Health Belief Model (Glanz, Rimer and Viswanath, 2008); the Transtheoretical Theory (Prochaska and Velicer, 1997); Self-Efficacy (Bandura, 1994); and the Theory of Planned Behaviour (Friedman, 2011).

Psychological DSME interventions focus on the therapeutic alliance between the therapist and people with diabetes, to improve their bio-psychosocial outcomes (Smith, 2012). We classified psychological interventions into the common psychotherapeutic models used in health-care settings: (i) supportive or counselling therapy (Rogers, 1976); (ii) cognitive behaviour therapy (Beck, 1976; Meichenbaum, 1977); (iii) brief psychodynamic psychotherapy (Malan, 1963); and (iv) interpersonal therapy (Klerman *et al.*, 1984). Studies with unclear model of intervention were also included if they used one or more psychological techniques that could be coded into the above classification. Techniques such as relaxation, activity scheduling, problem-solving, goal setting, contract setting, cognitive restructuring and stress management were classified as cognitive behaviour therapy (CBT) (Hawton *et al.*, 1989; Moorey and Williams, 1997). Techniques such as motivational interviewing and non-directive counselling were classified under counselling therapy. We reported only one analysis for studies with several intervention groups with the most intensive intervention as the

experimental one. Intensity was defined by approach (most intensive was group based rather than individual intervention), type of DSME intervention (most intense was psychologically followed by educational), number of sessions, and duration of the intervention.

2.4.3 Data extraction

The first reviewer, Arbaktun Mohamed (AM) screened all titles from the searches to exclude studies that were irrelevant. Following this, 3 reviewers AM, Kirsty Winkley (KW) and Emily Staite (ES) independently screened the title and abstracts using an eligibility checklist. The full texts of the potentially eligible studies were retrieved for full review and final selection. Studies written in a language other than English were translated by native speakers who are a specialist nurse (Chinese articles) and a pharmacist (Japanese article). Data for the studies were extracted by the first reviewer and verified by the second and third reviewers, (KW and ES), and finally, the fourth reviewer Khalida Ismail (KI) for accuracy and completeness. Any discrepancies in the extracted data were discussed by all 4 reviewers for a 100% consensus.

Data were extracted based on the following: (i) general information (author, title, citation and country); (ii) study characteristics (study design, number of participants at baseline and follow up, clinical subgroups, demographic details); (iii) intervention and setting (setting in which intervention delivered and description of it); and (iv) outcome data (baseline and follow up measure). Where applicable, effect size (Cohen's *d*) were extracted or calculated using the difference of means between two groups and divided by the pooled standard deviation.

2.4.4 Quality assessment

The quality of the studies was assessed using the Jadad score (Jadad *et al.*, 1996) by the first and second reviewers. The quality of included studies was assessed according to 3 appraisal elements: (i) selection bias (randomisation procedure and allocation concealment); (ii) blinding (masking of outcome assessor but not participants and therapist because DSME intervention cannot be concealed); and (iii) attrition bias (withdrawals or dropouts). Studies were then scored on a scale between 0 and 5. Studies scoring greater than 3 demonstrated high quality.

2.4.5 Data synthesis and analysis

Overview and characteristics of included studies are presented in the summary table (Table 2.2). Meta-analysis was not conducted due to the heterogeneity of the interventions, populations and outcome measurement. The primary outcome was an improvement in glycaemic control (HbA1c) (% or mmol/mol). Cohen's d effect size of HbA1c results was used to measure the magnitude of the difference in the outcome between the intervention and control groups, where a value of 0.2 represents a small effect size, 0.5 represents a moderate effect size, and 0.8 represents a large effect size (Cohen, 1988). Meanwhile, the secondary outcomes were other metabolic control measure, such as the body mass index (BMI) (kg/m^2), the cholesterol level (mmol/L), the fasting plasma glucose level (mmol/L), and the blood pressure (mmHg), as well as psychosocial variables such as self-reported quality of life, self-efficacy and level of depression.

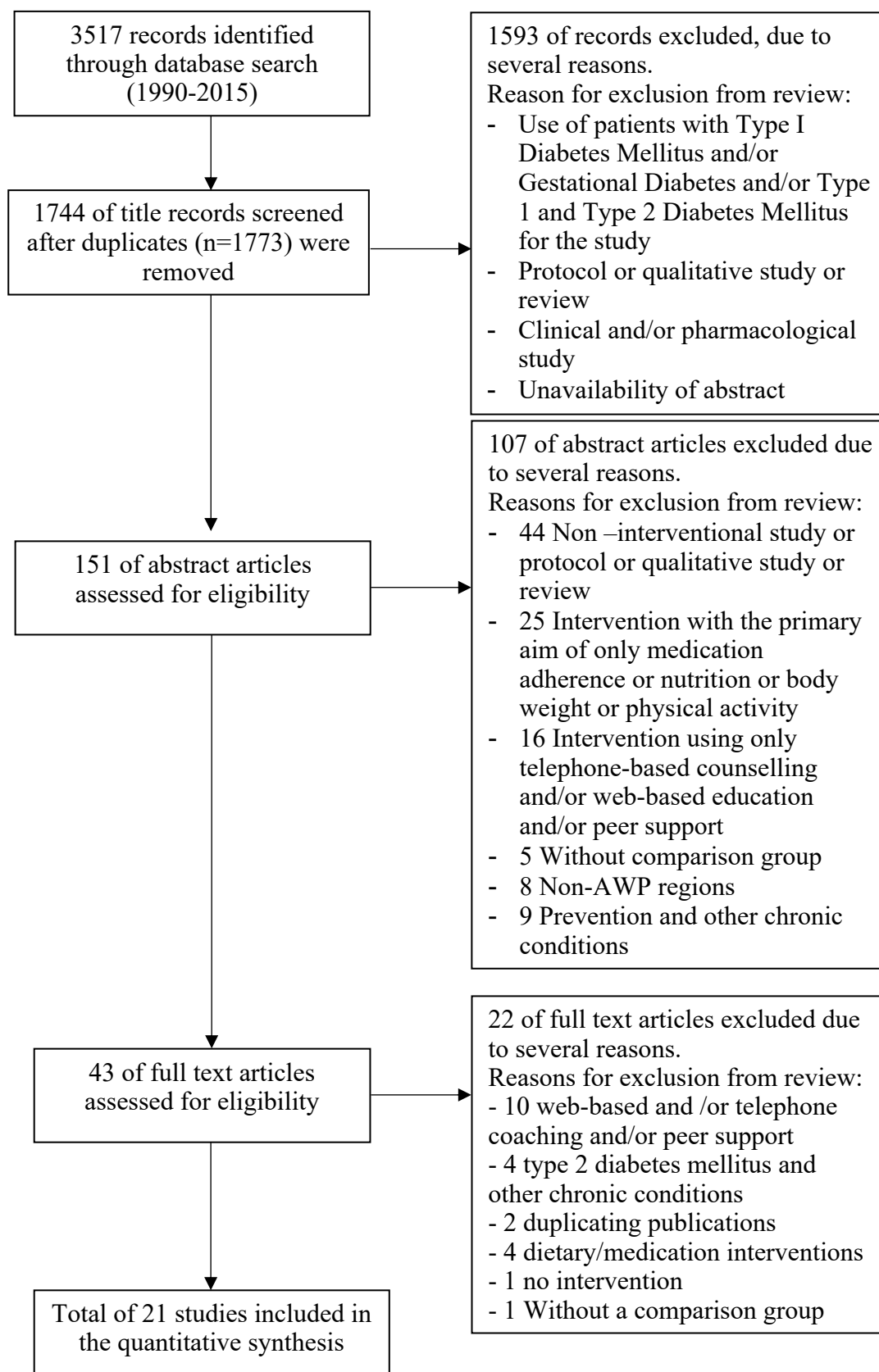
2.5 Results

The databases search yielded 3517 studies relevant to the search strategy. After the removal of duplications, a total of 1744 non-duplicated publications were screened, 151 abstracts were assessed for eligibility, and 43 publications requiring full-text review before a decision could be made. Of the 43 full-text articles assessed, 22 of the studies have been excluded, due to a number of reasons, such as were of web-based or telephone coaching or peer support interventions, having groups with a combination of type 2 diabetes and co-morbidities, duplicate publications (original Chinese article), were of dietary intervention or pharmacological intervention only, or studies without a comparison group.

Twenty-one studies fulfilled the inclusion criteria, and the study characteristics are presented in Table 2.2. The search process is illustrated in Figure 12. The interventions varied considerably according to the number and duration of sessions, however, the contents were mostly similar, with a focus on diabetes self-management.

The studies included in the recent review varies in the methodology used, thus the Jadad score was used to assess the quality of the journal publications in general. It provided guidelines to review included studies systematically within the various research context. Scoring elements of Jadad score are detailed in Table (2.3).

Figure 12: Stages of the systematic review: Diabetes Self-Management Education Interventions for People with Type 2 Diabetes Mellitus (T2DM) in the Western Pacific Region



2.5.1 Study characteristics

Twenty-one studies were analysed in this systematic review. Sixteen studies (Campbell *et al.*, 1996; Krass *et al.*, 2007; Shibayama *et al.*, 2007; Sun *et al.*, 2008; Wei *et al.*, 2008; Moriyama *et al.*, 2009; Sone *et al.*, 2010; Shi, Ostwald and Wang, 2010; Tan *et al.*, 2011; Zhou *et al.*, 2011; Li *et al.*, 2012; Liu *et al.*, 2012; Yuan *et al.*, 2014; Guo *et al.*, 2014; Chao *et al.*, 2015; Jaipakdee *et al.*, 2015) were RCTs; 4 (Yang *et al.*, 2007; Song *et al.*, 2012; Ng and Sim, 2014; Wong *et al.*, 2014) were an of observational matched cohort studies, and one was a retrospective cohort study (Roberts *et al.*, 2017).

The duration of the intervention ranged from 6 weeks to 18 months. Eight studies were conducted in China (Yang *et al.*, 2007; Sun *et al.*, 2008; Wei *et al.*, 2008; Shi, Ostwald and Wang, 2010; Zhou *et al.*, 2011; Li *et al.*, 2012; Liu *et al.*, 2012; Chao *et al.*, 2015), 3 in Japan (Shibayama *et al.*, 2007; Moriyama *et al.*, 2009; Sone *et al.*, 2010), 3 in Australia (Campbell *et al.*, 1996; Krass *et al.*, 2007; Roberts *et al.*, 2017), 2 in Hong Kong (Wong *et al.*, 2014; Yuan *et al.*, 2014), as well as 1 each in Singapore (Ng and Sim, 2014), Korea (Song *et al.*, 2012), Malaysia (Tan *et al.*, 2011) and Thailand (Jaipakdee *et al.*, 2015) respectively. The mean age of the study participants was 45 to 71 years old, with a majority (91%; n=21) of the studies having a mean population age of 55 years and above. In most of the studies in the review (91%; n=21), the glycated haemoglobin (HbA1c) was assessed as the primary outcome with an effect size (Cohen's d) ranging from 0.1 to 0.6, while other metabolic measures and psychosocial well-being or quality of life were measured as the secondary outcome. Of the 21 studies, there were a number of clinical subgroups among the populations studied: (i) 2 studies (9%; n=21) were conducted among elderly people; (ii) 4 (19%; n=21) included people with less than 5 years duration of having diagnosed with T2DM; (iii) 1 (4%; n=21) was conducted among overweight people with T2DM (BMI

> 23kgm³); (iv) 7 (30%; n=21) were implemented among people with T2DM with sub-optimal diabetes control, while the remaining 7 (30%; n=21) did not specify any specific clinical subgroup. Half of the interventions (53%; n=21) were conducted at a clinical setting, either hospital or primary care clinics, while the remainder were conducted in community settings such as community centres, nursing homes or both.

Two studies were translated into English from the original Chinese article (Zhou *et al.*, 2011; Li *et al.*, 2012). With regards to quality, 11 studies (Krass *et al.*, 2007; Moriyama *et al.*, 2009; Shi, Ostwald and Wang, 2010; Sone *et al.*, 2010; Tan *et al.*, 2011; Li *et al.*, 2012; Liu *et al.*, 2012; Guo *et al.*, 2014; Yuan *et al.*, 2014; Chao *et al.*, 2015; Jaipakdee *et al.*, 2015) were classified as ‘high’. Ten studies as ‘low’ (5 RCTs (Campbell *et al.*, 1996; Shibayama *et al.*, 2007; Sun *et al.*, 2008; Wei *et al.*, 2008; Zhou *et al.*, 2011) , 2 Non-RCTs (Song *et al.*, 2012; Wong *et al.*, 2014), 1 retrospective cohort study (Roberts *et al.*, 2017), and 2 were of abstracts only (Yang *et al.*, 2007; Ng and Sim, 2014).

2.5.2 Intervention characteristics

Fourteen studies (Campbell *et al.*, 1996; Sun *et al.*, 2008; Shi, Ostwald and Wang, 2010; Zhou *et al.*, 2011; Li *et al.*, 2012; Liu *et al.*, 2012; Song *et al.*, 2012; Wong *et al.*, 2014; Yuan *et al.*, 2014; Guo *et al.*, 2014; Ng and Sim, 2014; Chao *et al.*, 2015; Jaipakdee *et al.*, 2015; Roberts *et al.*, 2017) were group-based interventions, while 7 studies (Krass *et al.*, 2007; Shibayama *et al.*, 2007; Yang *et al.*, 2007; Wei *et al.*, 2008; Moriyama *et al.*, 2009; Sone *et al.*, 2010; Tan *et al.*, 2011) implemented an individual approach.

Fifteen interventions were classified as predominantly educational, with 10 using a combination of didactic and facilitative teaching (Campbell *et al.*, 1996; Krass *et al.*, 2007; Li *et al.*, 2008; Sun *et al.*, 2008; Sone *et al.*, 2010; Zhou *et al.*, 2011; Song *et al.*, 2012; Guo *et al.*, 2014; Yuan *et al.*, 2014; Chao *et al.*, 2015; Jaipakdee *et al.*, 2015), and 4 using didactic teaching alone (Yang *et al.*, 2007; Wei *et al.*, 2008; Ng and Sim, 2014; Roberts *et al.*, 2017). Six studies were grouped as predominantly psychological, with only one study explicitly stating that the intervention were implemented using the CBT and motivational interviewing (Moriyama *et al.*, 2009), whilst the remaining 5 were carried out using psychological techniques, 3 using CBT strategies such as problem solving and goal setting (Shibayama *et al.*, 2007; Liu *et al.*, 2012; Wong *et al.*, 2014), and 2 studies using counselling therapy (Shi, Ostwald and Wang, 2010; Tan *et al.*, 2011). None of the psychological intervention group studies have used a psychodynamic or interpersonal model of therapy. There were interventions delivered underpinned by various theories. Five studies were underpinned by the self-efficacy theory, 2 of these were educational (Zhou *et al.*, 2011; Ng and Sim, 2014) and 3 were of psychological interventions (Shi, Ostwald and Wang, 2010; Tan *et al.*, 2011; Wong *et al.*, 2014). In the 6 studies applying the psychological intervention only one study was underpinned by the transtheoretical theory (Moriyama *et al.*, 2009).

2.5.3 Assessment of quality

In general, most of the studies included were of reasonable methodological quality, and the abstract of the included studies were able to provide adequate information particularly on the aims, methods and findings of each study. Of twenty-one studies, 12 (60%, n=21) of the reviews scored three and above against the Jadad score, which were then categorised as high in quality. However, through a thorough evaluation of

the studies, the researcher has come across some flaws, resulting in a Jadad score of below three that may affect the credibility of the evidence provided. A number of studies have provided limited information on the randomisation strategies utilised (Campbell et al., 1996; Shibayama et al., 2007; Yang et al., 2007; Sun et al., 2008; Wei et al., 2008; Zhou et al., 2011). For example, a study by (Shibayama et al., 2007) investigating the effectiveness of individual counselling by a certified expert nurse to improve the biomedical outcomes among people with T2DM who did not receive insulin therapy in Japan. The authors claimed that the participants were randomised to either intervention or control group, but no specific strategies were reported either in the form of table of random numbers or computer-generated information.

Element with least description from the Jadad score was the blinding assessment. It was noted that none of the included studies described any form of double blinding (such as identical treatments). Furthermore, none of the trials explicitly explained any appropriate method of blinding implemented. Even though there was a lack of description regarding blinding of the included publications, a majority have described the numbers of withdrawals and dropouts. Correspondingly, in most of the studies, the data was analysed using the intention to treat principle, which helps to preserve the sample size, which is an important criterion to represent the statistical power.

With regards to ethical considerations, information regarding ethical approval was mentioned in all included studies, with a majority gaining informed consent prior to the commencement of the study. However, detailed explanation of other aspects, such as how the rights of the participants will be preserved during the intervention period, were omitted from the majority of the publications. Only three authors

(Moriyama *et al.*, 2009; Shi, Ostwald and Wang, 2010; Song *et al.*, 2012) explicitly explained the process of informing the participants regarding the voluntary nature of their participation, and their right to withdraw at any time of the research period, as well as any possible risks and benefits of the intervention that they were participating in. In summary, most of the studies are of good quality, where the study design, methods and data analysis were appropriate in achieving the aims and objectives of each study.

2.5.4 Impact of educational and psychological intervention on glycaemic control

Sixteen studies examined the HbA1c as an outcome to measure the impact of DSME (educational and psychological) interventions. Eight studies (50%; n=16) reported statistically significant improvements in glycaemic control, for both educational and psychological interventions. Four out of 8 studies (50%; n=8) (Campbell *et al.*, 1996; Sun *et al.*, 2008; Li *et al.*, 2012; Song *et al.*, 2012) were of group based interventions, demonstrating moderate effect size ranging from 0.5 to 0.6. Whilst, 6 out of 7 (85%; n=7) were of individual intervention studies (Krass *et al.*, 2007; Shibayama *et al.*, 2007; Yang *et al.*, 2007; Wei *et al.*, 2008; Moriyama *et al.*, 2009; Sone *et al.*, 2010), having a smaller effect size of HbA1c ranging from 0.1 to 0.2. Among the studies that yielded moderate (good) effect size, 4 studies (80%, n=5) (Campbell *et al.*, 1996; Li *et al.*, 2008; Sun *et al.*, 2008; Song *et al.*, 2012; Yuan *et al.*, 2014) represented high intensity programs (> 10 hours sessions), as defined in the systematic review of RCTs on behavioural interventions (Pillay *et al.*, 2015). In addition, 5 group based intervention studies reported significant improvement in HbA1c, and 2 of these (40%; n=5) (Li *et al.*, 2008; Sun *et al.*, 2008) reported moderate effect size.

2.5.5 Impact of educational and psychological intervention on psychological well-being, diabetes knowledge and self-management

Two studies (Campbell *et al.*, 1996; Chao *et al.*, 2015) measured diabetes knowledge using validated questionnaires. These include the 15-item diabetes knowledge scale (DKNA), and the Revised Diabetes Self-care Activities (RDSA) Questionnaires modified from the Diabetes Self-care Activities Questionnaire used in Malaysia. Only 1 (Chao *et al.*, 2015) demonstrated a significant difference between the intervention and the control group. Six studies (Shi, Ostwald and Wang, 2010; Tan *et al.*, 2011; Song *et al.*, 2012; Guo *et al.*, 2014; Ng and Sim, 2014; Chao *et al.*, 2015) measured at least one aspect of diabetes self-management. However, only 4 studies (Tan *et al.*, 2011; Song *et al.*, 2012; Guo *et al.*, 2014; Chao *et al.*, 2015) demonstrated statistically significant improvement in the intervention group.

Of 6 studies, 4 studies assessing psychosocial self-efficacy have shown statistically significant improvement (Moriyama *et al.*, 2009; Shi, Ostwald and Wang, 2010; Liu *et al.*, 2012; Guo *et al.*, 2014), and only 1 (Moriyama *et al.*, 2009) of these was carried out using an individual approach, while the other 3 were of group based (Shi, Ostwald and Wang, 2010; Liu *et al.*, 2012; Guo *et al.*, 2014). Five studies measured the quality of life using validated questionnaires (EQ5D, WHO-QOL26, SF-36 and Chinese version of DQOL), with 3 of these reporting statistically significant results; 1 study used an individual psychological intervention (Moriyama *et al.*, 2009) and 2 studies used group-based educational (didactic and facilitative) teaching (Zhou *et al.*, 2011; Jaipakdee *et al.*, 2015). However, the other 2 studies (Krass *et al.*, 2007; Shibayama *et al.*, 2007) reported no difference in the quality of life outcomes, and were of individual educational and psychological interventions respectively.

2.5.6 Impact of additional components, setting and speciality of the educators on glycaemic control.

There were 4 studies (Campbell *et al.*, 1996; Song *et al.*, 2012; Chao *et al.*, 2015; Jaipakdee *et al.*, 2015) which integrated practical sessions such as exercise classes and healthy diet preparation into the DSME intervention. Only 2 of 4 studies (Campbell *et al.*, 1996; Song *et al.*, 2012) reported moderate effect sizes for HbA1c. Furthermore, 5 studies (Moriyama *et al.*, 2009; Sone *et al.*, 2010; Liu *et al.*, 2012; Guo *et al.*, 2014) integrated telephone follow-ups as part of their intervention; only 1 study reported moderate effect size of HbA1c (Tan *et al.*, 2011). The professional background and speciality of the educators who delivered the interventions varied across the studies (reported only in 17 studies). Three studies (40%; n=8) (Campbell *et al.*, 1996; Sun *et al.*, 2008; Song *et al.*, 2012) were delivered by multidisciplinary team such as diabetes nurse educator, dietitian, podiatrist, general practitioner (GP) or clinical psychologist and achieved acceptable effect sizes (ranging 0.5 to 0.6) compared to interventions delivered by only one health care professional (11%; n=9) (Tan *et al.*, 2011) either trained nurse educator or physician or nutritionist with moderate effect size. Interventions implemented in the community or both settings (clinical and community) had moderate effect size (33%; n=9) (Sun *et al.*, 2008; Li *et al.*, 2012; Song *et al.*, 2012) and (100%; n=1) (Campbell *et al.*, 1996) respectively.

2.5.7 Integration of cultural sensitivity in the interventions

Most of the studies identified by this review have involved the delivery of educational, self-management and/or psychological interventions to people with T2DM from countries within AWP. However, from the examination of the intervention characteristics, none of them has specified specific cultural adaptations to address the needs of local individuals to support diabetes self-management. The only cultural concessions made and reported were 17 studies mainly conducted in the East and Southeast Asian countries and included translation of self-report outcome measurements, such as validated questionnaires, and delivery of interventions in native language (Yang et al., 2007; Shibayama et al., 2007; Sun et al., 2008; Wei et al., 2008; Moriyama et al., 2009; Shi, Ostwald and Wang, 2010; Sone et al., 2010; Tan et al., 2011; Zhou et al., 2011; Liu et al., 2012; Song et al., 2012; Guo et al., 2014; Wong et al., 2014; Yuan et al., 2014; Ng and Sim, 2014; Chao et al., 2015; Jaipakdee et al., 2015). Apart from that, among the 17 studies conducted in the non-English language speaking countries only 5 (30%; n=17) specifically mentioned that the topic or intervention pertaining to diet such as calorie counting activity, food exchange tables and individual diet plan are based on most common local foods and dishes (Sun et al., 2008; Wei et al., 2008; Sone et al., 2010; Tan et al., 2011; Li et al., 2012). Nevertheless, none of the above-mentioned studies discussed or developed their intervention based on any local customs, norms or religious practice nor did they involve local people in the development of the intervention.

Table 2.2: Overview of the eligible studies examining the effects of Diabetes Self-Management Education (DSME) interventions for people with Type 2 Diabetes Mellitus (T2DM) in the Asian Western Pacific (AWP) region.

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Campbell/ Australia/ RCT/ 1996 (Campbell <i>et al.</i> , 1996)	33/19	<5 years' duration of T2DM	59 (1.4)	Educational (didactic and facilitative teaching) for 12 months	12 monthly individual education sessions + quarterly group- based education (lectures on diabetes self- management & practical sessions on food selection) by RN and MDT (dietitian, occupational therapist and podiatrist)	Educational (didactic teaching) for 12 months	2 hours individual education sessions by RN and dietitian	0.6	↑ Diabetes knowledge score: $p=0.361$ (ND)	12	Both	Low

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Chao/ China/ RCT/ 2015 (Chao <i>et al.</i> , 2015)	100/100	Elderly (age NS)	69 (6.4)	Educational (didactic and facilitative teaching) for 18 months	18 monthly group education sessions (lectures and a tailored exercise programme) by manager and health service centre manager; speciality NS	Usual care for 18 months	Usual care; regimen and speciality NS	NR	↑ Diabetes knowledge score: $p < 0.0001$ ↑ Psychological health status: $p = 0.034$ ↑ Healthy diet: $p = 0.012$ ↑ Physical activity: $p = 0.013$ ↑ SMBG: $p = 0.004$	18	Clinical	High
Guo/ China/ RCT/ 2014 (Guo <i>et al.</i> , 2014)	1511/1289	HbA1c: $>7.5\%$ + 2 or more OADs	57 (10.4)	Educational (didactic and facilitative teaching) for 4 months	6 group education sessions at week 0,2,4, 8,12 & 16 (7 topics on self- management) + 3 telephone follow ups at week 1,3 & 6 by RN	Educational (didactic teaching) for 4 months	6 group education sessions (lectures on self- management) by RN	0.2	↑ SMBG: $p < 0.05$ (ND) ↑ C-DMSES: $p = 0.0001$ ↑ SDSCA: $p < 0.001$ ↑ MMAS: $p = 0.0002$	4	Clinical	High

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Jaipakdee/ Thailand/ Cluster RCT/ 2015 (Jaipakdee <i>et al.</i> , 2015)	403/384/378	HbA1c: $\geq 7\%$ within 2 months before program	61.3 (9.7)	Educational (didactic and facilitative teaching) for 6 months with psychological support	6 monthly sessions for 3 hours (diabetes education and skill learning (step-by-step) with psychological support called 5C intervention (constructing a problem definition; collaborative goal setting; collaborative problem solving; contracting for change; continuing support) by trained nurses and healthcare professionals	Usual healthcare over 6m	Physical examination, monitoring of blood sugar levels, individual health education & consultation from a registered nurse and/or other healthcare provider	0.2	↓HbA1c: $p=0.334$ (NS) ↓FPG: $p=0.001$ ↑Health behaviour score: $p<0.001$ ↓Weight: $p=0.001$ ↓PHQ-9: $p=0.495$ (NS) ↑QOL: $p<0.001$	3 & 6	Clinical	High

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Krass/ Australia/ RCT/ 2007 (Krass <i>et al.</i> , 2007)	335/289	HbA1c: ≥7.5%+1 OAD/ insulin; Hba1c: ≥7.0%+1 OAD or insulin/1 AHT /angina or lipid-lowering drug	62 (11.0)	Educational (didactic and facilitative teaching) for 6 months	5 individual education sessions on self- management by pharmacist + daily self- monitoring blood glucose level	Educational (didactic teaching) for 6 months	2 individual education sessions (at beginning and end of the intervention) by pharmacist	0.1	↓ BMI: $p=0.37$ (ND) ↑ QOL (EQ- 5D): $p=0.07$ (ND)	6	Community	High
Li/ China/ RCT/ 2012 (Li <i>et al.</i> , 2012)	280/248	NS	65 (12.2)	Educational (didactic and facilitative teaching) for 18 months	12 monthly health education club (education session for 2 hours on self- management) +12 telephone follow up (twice monthly) for 6 months + quarterly outdoor activity; speciality NS	NS	Regimen and speciality NS	0.5	↓ FPG: $p=0.004$ ↓ post-prandial glucose: $p=0.003$ ↓ HbA1c: $p=0.004$	18	Community	High

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Liu/ China/ RCT/ 2012 (Liu <i>et al.</i> , 2012)	233/176	NS	62 (9.8)	Psychological (CBT) for 12 months	12 monthly group visit sessions (2.5 hours each sessions includes lectures, group discussion, action plan) by general practice team (one GP, one physician and one RN)	Usual care for 12 months	Usual care by GP	NR	↑ Diabetes Self-Efficacy Scale (Stanford Patient Education Research Centre): $p=0.02$ ↑ Physical activity: $p=0.0001$ ↑ Depression: $p=0.43$	12	Community	High
Moriyama/ Japan/ RCT/ 2009 (Moriyama <i>et al.</i> , 2009)	75/65	NS	66 (8.9)	Psychological (CBT & counselling therapy using motivational interviewing) underpinned by transtheoretical model for 12 months	1 pre-readiness assessment (transtheoretical model) + 12 monthly individual education sessions (interview using motivational interviewing) each session lasts for 30 minutes on self- management + 6 telephone follow up every fortnight + 1 education session for	Usual care for 12 months	Usual care + written education materials on clinical characteristics, treatment available & self- management measures	0.1	↑ QOL (WHO- QOL26): $p=0.005$ ↑ Self-Efficacy: $p=0.0001$ ↑ Physical activity: $p=0.520$ (ND) ↑ Lose weight: $p=0.004$ ↑ Healthy diet: 0.046	12	Clinical	High

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
					carer + 12 monthly individual goal setting by RN							
Ng/ Singapore/ Non-RCT/ 2014 (Ng and Sim, 2014)	50	Newly diagnosed duration NS	NR	Educational (didactic teaching) underpinned by self-efficacy theory for 3 months	Group education session and regimen; speciality NS	Educational (didactic teaching) for 3 months	Individual education sessions; regimen and speciality NS	0.1	↑ Physical activity: $p>0.05$ (ND) ↑ Self-foot assessment: $p=$ 0.984 (ND) ↑ Healthy diet: $p>0.05$ (ND) ↑ Quit Smoking: $p>$ 0.05 (ND)	3	Clinical	Low
Roberts/ Australia/ Retrospective cohort study/ 2017 (Roberts <i>et al.</i> , 2017)	219	NR	62 (12)	Educational (didactic teaching) for 12 months	1 hour clinical assessment + 6 weekly group education each session last for 2 hours + proactive recalls at 3, 6, and 12 months by allied health professionals (dietitian, podiatrist) led by the diabetes nurse-educator	Educational (didactic teaching) for 12 months	1 hour clinical assessment + attended at least 1 group education session (2 hours) + proactive recalls at 3, 6, and 12 months by same speciality in the intervention group	0.33	↑ Cholesterol: $p<0.001$ ↑ BMI: $p=0.003$ ↑ QOL: $p<0.001$ ↑ Psychological distress: $p=0.016$ ↑ HbA1c: $p=0.134$ (NS)	12	Community	Low

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Shi/ China/ RCT/ 2010 (Shi, Ostwald and Wang, 2010)	157	Newly diagnosed \leq 12 months at recruitment period	46 (6.9)	Psychological (counselling therapy) underpinned by self-efficacy theory for 1 months	4 weekly group education sessions for 2 hours (counselling on diet & exercise, peer role model for SMBG, persuasion & reinforcement strategies to eliminate barriers) + 2 weekly telephone counselling sessions for 5- 15 minutes (month 4) by RN	Usual care for 4 months	Treatment as usual; regimen and speciality NS	NR	\uparrow DMSES: $p=0.0001$ \uparrow SDSCA: $p=0.0001$	4	Clinical	High
Shibayama/ Japan/ RCT/ 2007 (Shibayama <i>et al.</i> , 2007)	148/134	HbA1c: 6.5%- 8.5%	62 (7.5)	Psychological (CBT) for 12 months	12 monthly individual counselling sessions for 25 mins (self- management and stress management) by certified expert nurse	Usual care for 12 months	Usual monthly follows up by physician	0.2	\uparrow QOL (SF-36): $p > 0.05$ (ND) \uparrow PAID: $p=0.57$ (ND)	12	Clinical	Low

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Sone/ Japan/ RCT/ 2010 (Sone <i>et al.</i> , 2010)	2033/1304	HbA1c: ≥ 6.5%	59 (6.9)	Educational (didactic and facilitative teaching) for 12 months	Self- management written educational materials + 12 self- managements individual education (10 minutes' additional session from control group) during routine follow up by MDT (physician, RN, dietitian) + fortnightly telephone follows up by MDT (RN, dietitian & clinical psychologist) + progress diary and pedometer	Educational (didactic teaching) for 12 months	Written educational materials and usual routine follow up by physician; regimen NS	0.1	↑ Low fat diet: $p=0.30$ (ND) ↑ Physical activity: $p=0.037$	48	Clinical	High

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Song/ Korea/ Non-RCT/ 2012 (Song <i>et al.</i> , 2012)	40/37	Elderly (age NS)	71 (4.8)	Educational (didactic and facilitative teaching) for 3 months	12 weekly group education sessions (lectures on self- management) for 1 hour + 24 biweekly exercise classes for 2 hours + one-to- one counselling & instruction sessions at the end of the intervention by a RN and 2 assistants; speciality NS	Usual care for 3 months	Usual care; regimen NS	0.5	↑ DSMB: $p=0.006$ ↑ FPG: $p=0.263$ ↑ Total CHO: $p=0.782$ ↑ Triglyceride: $p=0.021$ ↑ HDL-C: $p=0.024$ ↑ LDL-C: $p=0.976$ ↑ body weight (kg): $p<0.001$ ↑ BMI: $p<0.001$	3	Community	Low
Sun/ China/ RCT/ 2008 (Sun <i>et al.</i> , 2008)	150	Over-weight with BMI: $\geq 23 \text{ kg m}^{-3}$	51 (1.0)	Educational (didactic and facilitative teaching) for 6 months	6 monthly group education sessions (lectures on self- management & healthy eating with meal plans) by nutritionist + 24 weekly self- monitoring blood glucose follow up sessions and	Educational (didactic teaching) for 6 months	Monthly education sessions (diet and physical instruction only) by nutritionist	0.6	↑ Low-carb diet: $p=0.634$ (NS) ↑ High fibre intake: $p=0.010$ ↑ Physical activity (PCS): $p=0.004$ ↑ Mental health (MCS): $p=0.017$	6	Community	Low

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
					diet consultations for 30 mins by dietitian and medical evaluation by physician if needed + low glycaemic meal replacement (powdered formula) for breakfast							
Tan/ Malaysia/ RCT/ 2011 (Tan <i>et al.</i> , 2011)	164/151	HbA1c: >7.0%	54 (10.3)	Psychological (counselling therapy) underpinned by self-efficacy theory for 3 months	2 monthly individual education sessions (self-management and problem solving skills using verbal persuasion, role modelling, physiological state) + 1 telephone follow up by RN	Usual care for 3 months	Follow up at 3 months by physician	0.5	↑ Diabetes knowledge score: $p=0.001$ ↑ SMBG: $p=0.001$ ↑ MMAS: $p=0.008$ ↑ Low fat diet: $p>0.05$ (NS) ↑ Physical activity: $p=0.001$ ↑ BMI: $p>0.05$ (NS)	3	Clinical	High

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Wei/ China/ RCT/ 2008 (Wei <i>et al.</i> , 2008)	456/338	NS	69 (9.7)	Educational (didactic teaching) for 8 months	8 monthly individual education sessions (lecture and discussion of diet plans and self- management activities) by family physician	Usual care for 8 months	Treatment as usual; regimen and speciality NS	NR	↑ FPG: $p=0.002$ ↑ BMI: $p=0.124$ (ND) ↑ lose weight: $p=0.038$	8	Community	Low
Wong/ Hong Kong/ Observational matched cohort study/ 2014 (Wong <i>et al.</i> , 2014)	2282	HbA1c: $\geq 7.0\%$	65 (10.7)	Psychological (CBT) underpinned self-efficacy theory for 12 months	Total of 5 hours' group education sessions on self- management (goal setting, problem solving, stress management) by health care professional; speciality NS	Usual care for 12 months	Received diabetes follow up from Hong Kong Hospital Authority GOPC; speciality NS	0.1	↑ Decrease visit to GOPC: $p=0.001$ ↑ Decrease visit to SOPC: $p=0.001$ ↑ Decrease visit to ED: $p=0.865$ (ND) ↑ Decrease inpatient admission: $p=0.615$ (ND)	12	Clinical	Low
Yang/ China/ Non-RCT/ 2007 (Yang <i>et al.</i> , 2007)	113	NS	48-71	Educational (didactic teaching) for 6 months	1 introductory education session by endocrinologist + 12 fortnightly individual Education sessions by physician	Educational (didactic teaching) for 6 months	1 Introductory education session + 6 or 12 telephone consultations once every 1 or 2 months by physician	0.4	↑ BMI: $p>0.05$ (ND)	6	Clinical	Low

First author/ Country/ Type of study/ Year	Number of participants recruited/ at follow up	Clinical subgroup	Mean age (SD or range), years	Type and duration of intervention (intervention group)	Regimen in intervention group and speciality of therapist	Type and duration of intervention (control group)	Regimen in control group and speciality of therapist	Effect size of HbA1c (d)	Other outcomes (intervention vs control)	Follow-up (months)	Setting (community vs. clinical)	Quality (Jadad Score)
Yuan/ Hong Kong/ RCT/ 2014 (Yuan <i>et al.</i> , 2014)	88/76	> 1-year duration of T2DM	58 (8.3)	Educational (didactic and facilitative teaching) for 2 months	8 weekly group education sessions (lectures on self- management) for 2 hours + self- management guidance by nutritionist	Usual care for 2 months	Received standard medical nutrition advice; regimen and speciality NS	0.3	↑ Lose weight: $p=0.066$ (ND) ↑ BMI: $p=0.019$	2	Community	High
Zhou/ China/ RCT/ 2011 (Zhou <i>et al.</i> , 2011)	280/248	NS	65 (12.2)	Educational (didactic and facilitative teaching) underpinning self-efficacy theory for 18 months	12 monthly group education session for 2 hours (self- management) +12 telephone follow up (fortnightly) for 6 months + quarterly outdoor activities; speciality NS	NS	Regimen and speciality NS	NR	↑ Self anxiety scale: $p<0.001$ ↑ Self-rating depression scale: $p=0.001$ ↑ QOL: $p<0.001$	18	Community	Low

↑, improvement; ↓, worsening; ND, no difference; NS, not specified; T2DM, type 2 diabetes mellitus; MDT, multi-disciplinary team; AHT, anti-hypertensive; NR, not reported; RN, registered nurse; OAD, oral anti-diabetic agent; SMBG, Self-monitoring Blood Glucose; CBT, Cognitive Behaviour Therapy; DMSES, Diabetes Management Self-Efficacy Scale; C-DMSES, Chinese Diabetes Management Self-Efficacy Scale; SDSCA, Summary of Diabetes Self-Care Activities; MMAS, Morisky Medication Adherence Scale; DSMB, Diabetes Self-management Behaviour; PCS, Physical component summary of Short Form Health Survey (SF 36); MCS, Mental component summary of Short Form Health Survey (SF 36); QOL, Quality of Life; SAS, Self-Anxiety Scale; SDS, Self-Rating Depression Scale; EQ-5D, EuroQol-5 Dimension Questionnaire; GOPC, General Outpatient Clinic; SPOC, Specialist Outpatient Clinic; ED, Emergency Department; PAID, Problem Areas in Diabetes Questionnaire; BP, Blood Pressure; BMI, Body Mass Index; HbA1c, Hemoglobin A1c; DKNA, Diabetes Knowledge; HR, Heart Rate; C-DIMES, Chinese version of the Diabetes Self-efficacy Scale; PAIDS, Problem Areas in Diabetes Scale; RDSA, Revised Diabetes Self-care Activities; IMT, Intima-media thickness; DC, distensibility coefficient; CC, compliance coefficient; PWV, pulse wave velocity; PHQ-9, patient health questionnaire; d, Cohen'.

Table 2.3: Quality of the 21 studies as assessed by the Jadad score.

Study	Randomisation	Appropriated randomisation utilised	Blinding present	Appropriated blinding method utilised	Description of withdrawals and dropouts	Score	Quality (Jadad Score)
(Campbell <i>et al.</i> , 1996)	1	0	0	0	1	2	Low
(Chao <i>et al.</i> , 2015)	1	1	0	0	1	3	High
(Guo <i>et al.</i> , 2014)	1	1	0	0	1	3	High
(Jaipakdee <i>et al.</i> , 2015)	1	1	0	0	1	3	High
(Krass <i>et al.</i> , 2007)	1	1	0	0	1	3	High
(Li <i>et al.</i> , 2012)	1	1	0	0	1	3	High
(Liu <i>et al.</i> , 2012)	1	1	0	0	1	3	High
(Moriyama <i>et al.</i> , 2009)	1	1	0	0	1	3	High
(Ng and Sim, 2014)	0	0	0	0	0	0	Low
(Roberts <i>et al.</i> , 2017)	0	0	0	0	1	1	Low
(Shi, Ostwald and Wang, 2010)	1	1	0	0	1	3	High

Study	Randomisation	Appropriated randomisation utilised	Blinding present	Appropriated blinding method utilised	Description of withdrawals and dropouts	Score	Quality (Jadad Score)
(Shibayama <i>et al.</i> , 2007)	1	0	0	0	1	2	Low
(Sone <i>et al.</i> , 2010)	1	1	0	0	1	3	High
(Song <i>et al.</i> , 2012)	0	0	0	0	1	1	Low
Sun/ China/ RCT/ 2008 (Sun <i>et al.</i> , 2008)	1	0	0	0	1	2	Low
Tan/ Malaysia/ RCT/ 2011 (Tan <i>et al.</i> , 2011)	1	1	0	0	1	3	High
(Wei <i>et al.</i> , 2008)	1	0	0	0	1	2	Low
(Wong <i>et al.</i> , 2014)	0	0	0	0	0	0	Low
(Yang <i>et al.</i> , 2007)	1	0	0	0	1	2	Low
(Yuan <i>et al.</i> , 2014)	1	1	0	0	1	3	High
(Zhou <i>et al.</i> , 2011)	1	0	0	0	0	1	Low

2.6 Discussion

2.6.1 Discussion

This systematic review provides evidence of the effectiveness of DSME interventions on glycaemic control for people with T2DM in the AWP region. A total of 21 studies were identified of implementing interventions with various educational or psychological therapeutic approaches and modes of delivery. DSME is well integrated in the western developed countries, and this review highlights the growing number of interventions being developed in the AWP region, with positive impacts on glycaemic control for people with T2DM living in this area, compared to relying on medical intervention alone.

Compared to one-to-one interventions, it was found that most group-based DSME interventions implemented provided good effect on glycaemic control, particularly for interventions conducted in 10 hours or more (high-intensity interventions). Interventions that integrated practical sessions reported an exceptional clinical improvement in glycaemic control (moderate effect sizes Cohen's $d > 0.5$). There was a trend from 2007 onwards towards multidimensional interventions (involving facilitative teaching and psychological elements), rather than on didactic teaching alone. There is little evidence to recommend a specific theoretical model as the most effective for DSME from the available analysis, however, self-efficacy theory has been widely used, providing the team with some understanding on how intervention components promote behavioural modification or lifestyle change, which may help improve clinical outcomes as only one-third of the included studies measured at least one aspect of diabetes self-management. Despite the small proportion of studies, they generally reported positive effects for glycaemic control.

No direct comparison can be made between the present systematic review and any other review specifically conducted in the AWP region, as there are none. However, this was consistent with the review in the Western countries by (Chrvala, Sherr and Lipman, 2016), synthesising 118 RCTs, which demonstrated that a combination of group and active participation approach in DSME improve diabetes metabolic outcomes, where the mean reduction of HbA1c was -1.01 (SD=0.6) for group-based interventions compared to the overall interventions -0.74 (SD=0.63). Seventy percent of the included trials had more than 10 hours of contact hour between the learners and the educators, and these also demonstrated significant improvements on HbA1c level. Another recent systematic review and meta-analysis of group-based DSME RCTs by (Steinsbekk *et al.*, 2012) concluded that interventions conducted with longer hours (19 to 52 hours), which were delivered in 6 to 10 sessions over 10 months of intervention, have proven to be more beneficial in optimising blood glucose control. Longer contact hours commonly employed through continued or on-going education enhance learning by allowing knowledge and understanding to grow gradually.

Findings from a systematic review and meta-analysis of diabetes education RCTs conducted among Chinese adults with T2DM revealed that better glycaemic control (HbA1c) was achieved by on-going regular education sessions (weighted mean difference (WMD)= -2.02%/-22mmol/mol, 95% CI, [-2.38, -1.64]/ [-26.0, -17.9]) compared to intensive short-duration education sessions (WMD = -1.83%/-20mmol/mol, 95% CI [-2.65, -1.00]/[-29.0, -10.9]) (Choi *et al.*, 2016). These (group-based and longer contact hours) strategies, are acceptable and may promote reinforcement and an enhanced relationship between the participants and the facilitator among people of Asian origin in the AWP region, to maximise the effect of interventions to improve self-management and make lifestyle change.

The studies included generally adopted a facilitated teaching method, similar to the Western studies, and therefore the findings are generally consistent with the review by (Norris, Engelgau and Narayan, 2001) synthesising RCTs of self-management training intervention for people with T2DM, which concluded that participatory as compared with didactic teaching approaches alone were more effective in improving glycaemic control.

It is worth noting that delivery of DSME, which involves more than 1 member of the multidisciplinary team, may contribute to effectiveness, though this has yet to be confirmed in RCTs and observational studies according to a recent review (Chrvala, Sherr and Lipman, 2016). Findings from a systematic review of RCTs and comparative studies of DSME among African Caribbean and Hispanic Latin America women, demonstrated that 40% (n=13) of the pooled successful interventions (total studies included= 38), were of group and hospital-based interventions, incorporating a problem-solving approach with frequent and multiple sessions, as well as having a dietitian as one of the educators. This review suggested that a psychosocial approach has successfully addressed their psychological needs and beliefs regarding diabetes, and was able to empower them to deal with cultural norms and barriers towards achieving optimal lifestyle modifications.

It was unclear what the specific cultural elements of the included studies in the recent review, but all the non-English speaking countries implemented the DSME interventions in their mother tongues, while the questionnaires used to evaluate the interventions were translated and validated. This finding is consistent with existing systematic reviews of DSME in developing countries (Iran, Argentina, Turkey, China, Malaysia, South Africa and India), where most of the studies were carried out using a quasi-experimental design, demonstrating positive impact on behaviour change and

glycaemic control where it is linguistically acceptable (Dube *et al.*, 2015), however, deep cultural factors were not reported in the included studies. The importance of applying specific cultural lifestyle context in diabetes education interventions is also supported by a review, synthesising RCTs of T2DM prevention interventions in developing countries. This recommended that interventions incorporating deeper cultural aspects, such as common food preferences and type of cooking, common cultural ceremonies, as well as beliefs in complementary medicine may promote and enhance sustainability (Rawal *et al.*, 2012).

Only a few interventions included reports on special training for the educators. This is aligned with 2 systematic reviews of DSME for people with T2DM among adults in China (RCTs) (Lou *et al.*, 2011), and adults in developing countries (mostly quasi-experimental study) (Dube *et al.*, 2015), where nothing was mentioned on the training among the educators in China, while only a few reported specific details among studies in developing countries. Training of the educators is important in DSME to ensure the quality of the delivery in accordance to the comprehensive written curriculum.

2.6.2 Limitations

This review has several limitations. There is a possibility of publication bias as only published data was included. Fourteen studies (70%; n=21) included in the analysis had less than 12 months of follow up; therefore, long-term outcomes could not be assessed. Apart from that, the assessment of psychosocial outcomes in all studies was based on self-report questionnaires, which may include some bias. This review included non-randomised study designs, and was carried out using a discursive analysis rather than meta-analysis, due to the heterogeneity in both the interventions and outcome measure, as well as the difference in populations and settings. In terms of outcomes, this review mainly focuses on glycaemic control (HbA1c), due to the issue of extracting or calculating the effect size when the secondary outcomes were made using different measure, such as for diabetes knowledge, quality of life, self-efficacy, adherence and physical activity.

Related to the usage of the Jadad scoring system, despite being simple and easy to use with known reliability and external validity, there are some flaws in the scale. It should be noted that the scoring system does not address the appropriateness of data analysis or allocation concealment (which is one of the parameters to avoid bias in any research), or the assessment of intention-to-treat analysis lead to invalidating of the trials assessed where the findings should be interpreted with caution. Apart from that, it focuses too much on blinding, which is challenging in RCTs with complex interventions.

Although being a gold standard status in research design, blinding in most complex intervention RCTs are often not feasible. Complex intervention research such as DSME intervention trials are mainly conducted to determine effectiveness rather

than efficacy in the traditional RCTs, and often measure complex outcomes as well as consisting of multiple interactive elements that make it challenging to blind (Mustafa, 2017). Although randomisation was implemented, there is still a potential of the existence of confounding bias, either consciously or unconsciously, which may give a negative impact on the integrity of the complex intervention trials. In response to that, (Kahan et al., 2014) proposed the blinded outcome assessment, as a way to reduce this type of bias in complex intervention trials, in which the outcome assessor is blind to which arm (intervention or control group) the participants belong to.

Several limitations were identified as discussed. However, these did not distort the quality of the evidence produced. The findings of this review exhibit a clear understanding of the complexity of DSME intervention specifically to T2DM. However, the evidence available from this systematic review might not be sufficient to inform change of practice culturally in Malaysia healthcare setting, as the number of studies conducted in countries with more or less the same way of living was limited (only 1 study conducted in Malaysia, Singapore and Thailand respectively). Therefore, it could be argued that although the findings of the studies in this review provided clear evidence of the practical approach for DSME among the Asian Western Pacific region, a lack of report in the cultural context means that this evidence may not be adequate to inform the development of MY DEUMI, particularly in terms of cultural adaptation.

2.6.3 Practice Implications

This review may guide healthcare providers or policymakers in designing future culturally tailored interventions for people with T2DM in the AWP region. Successful interventions are likely to be group based, include active participation and have longer contact hours, but most studies did not provide sufficient information regarding cultural acculturation in the interventions. Therefore, more research is needed to determine how to address specific cultural beliefs and attitudes towards diabetes among Asians.

For example, the small feast culture common to Asian culture may be a barrier for people with T2DM to achieve optimal glucose control. This was demonstrated by an ethnographic study among the Middle Eastern people in the United Arab Emirates (UAE), which demonstrated that providing meals to strangers, guests and friends is a way to minimize social gap (Baglar, 2013), and the expectation is that all guests should eat all food provided. This infrequently happens in the Western cultures, where meals are only generally offered to close friends, family and guests (Douglas, 1975).

Apart from that, this review demonstrated that interventions incorporating ‘hands-on’ sessions were more effective, as compared to educational (didactic teaching and/or facilitated teaching) alone. This study recommended that more RCTs should be conducted with additional outcome measure of behavioural change and coping skills. A number of included studies demonstrated the effectiveness of DSME for people with T2DM to self-manage their condition, however, most of the positive impacts were either immediate or short-term. Therefore, future research needs to focus on how to maintain the effects for longer, as well as promoting the sustainability of the intervention.

2.7 Conclusion

This review identified and summarised the available evidence within the AWP from 21 studies on the effectiveness of DSME, to improve diabetes self-management in this region. The results suggest that overall group based DSME is associated with improved clinical and psychosocial outcomes, and interventions underpinned by behavioural theory with longer contact hours, as well as the inclusion of active, hands-on participatory sessions can maximise the potential benefit of these interventions. Likewise, involving the participation of a multidisciplinary team may also be important. However, what we do not yet know is how to target DSME in this region so that it is culturally appropriate, and whether beliefs and attitudes towards diabetes in ethnically diverse AWP communities are being addressed and how this is achieved. We can conclude that standardised DSME interventions or specific guidelines in this region was limited, therefore, there is an urgent need to develop DSME and make it accessible to people with T2DM in the AWP countries.

2.8 Summary

This chapter identified that DSME interventions are an effective method to assist people with T2DM in optimising glycaemic control, in the AWP region, which includes Malaysia. Group-based intervention with longer contact hours (> 10 hours), and inclusion of practical sessions may lead to a positive and effective diabetes self-management. In addition, more emphasis on contextual and deep cultural factors may improve the development of DSME interventions in the future.

The next chapter will explore the needs (barriers and facilitators of effective self-management) of Malaysians recently diagnosed with T2DM, in order to support their diabetes self-management.

Chapter 3 : Perceived Barriers and Facilitators of Effective Diabetes Self-Management Among Malaysians with Newly Diagnosed Type 2 Diabetes Mellitus: A Qualitative Study

3.1 Chapter scope

This chapter presents the views and experiences of diabetes self-management of adults with T2DM from Malaysia. The chapter is divided into 5 sections. The first section details the background and aims of this qualitative study. The second section discusses the methods involved. The third section details the results of the interviews in exploring participants' experiences and views regarding their self-management, particularly on the barriers and facilitators of diabetes self-management. Finally, the findings from this chapter are discussed, which include the way they might inform the development of the MY DEUMI educational intervention.

3.2 Introduction

In recent years, the development of health interventions has been increasingly being informed by evidence from qualitative and quantitative research studies. Qualitative evidence may provide alternative data through an inductive approach to identify appropriate and feasible elements that may become the targets of future interventions, or to further explain findings from quantitative research. Curry 2009 argued that qualitative methods should be considered in order to explore a phenomenon that is challenging to be investigated quantitatively, and to be able to understand a gap or research problem comprehensively. Another supportive argument (Meissner, 2011) is that qualitative exploration can be implemented either alone or in conjunction with quantitative methods during any phase of health research because it may provide data that goes beyond a single approach to a research question.

Within this thesis, a qualitative study was selected, so that information and understanding of the psychosocial context of the people who may go on to use a new intervention could be obtained. Moreover, this method assists with the interpretation of their opinions and experiences regarding diabetes self-management, which will be useful for developing the MY DEUMI intervention and may highlight elements that may affect its feasibility and acceptability.

To date, most research from Malaysia are focused on the clinical management of people who have had T2DM of varying duration, whereas there is limited evidence targeting people who are newly diagnosed. Concentrating on this population is important, as improving self-management in this group may have a greater long-term impact in terms of reducing morbidity. Thus, exploring the perceptions and views of diabetes self-management in this group may bring out essential information in

designing culturally tailored interventions as the Western model of diabetes education may not adequately support Malaysians with T2DM.

Generally, diabetes education is delivered in the form of a one-day group lecture (10 to 15 people), either by a registered dietician, a diabetes nurse, or a physician at follow-up consultations in the Malaysian primary care setting. Therefore, there is a need to determine which delivery method will work best, and what the essential content should be to support self-management. Findings from the study may shed a light on the critical factors that need to be considered when developing the MY DEUMI intervention for adults recently diagnosed with T2DM in Malaysia.

3.3 Aims of the study

The main aim of this study is to explore the views and experiences of people with a recent diagnosis of T2DM, regarding their diabetes self-management. A qualitative methodology has been selected to capture the wide range of thoughts and opinions among the participants. The aim of the study is to understand what additional support is required for people to make lifestyle change. The findings and conclusion of this qualitative exploration were needed to contribute to the development of MY DEUMI diabetes education intervention for people newly diagnosed with T2DM in Malaysia.

Research questions

The following statements are the research questions this thesis aims to answer:

1. What are the experiences regarding self-management for Malaysians who were newly diagnosed with T2DM?
2. What are the challenges encountered by patients in their daily diabetes self-management?
3. What support do people with T2DM in Malaysia require for diabetes self-management and how is this related to their glycaemic control?

3.4 Methods

3.4.1 Study design and setting

This study was carried out using a qualitative design, through either face-to-face or audio-telephone semi-structured interviews with adults with T2DM. The study was conducted at diabetes primary care clinics in the Southern Peninsular Region of Malaysia, between end of February and mid of June 2016.

3.4.2 Participants

Purposive sampling was used to recruit potential participants from the primary care clinic to ensure heterogeneity of data in terms of sociodemographic (age, ethnicity, education level and occupational status). The inclusion criteria for the study are as follows: (i) adults aged more than 18 years with diagnosis of T2DM less than 3 years from March 2016; (ii) able to speak Malay or English fluently; (iii) with or without the prescription of insulin and/or oral anti-hyperglycaemic agents (OHAs).

3.4.3 Qualitative procedure

Ethical approval was obtained from both the Psychiatry, Nursing and Midwifery (PNM) Research ethics subcommittee (RESC) at King's College London, and the Medical Research and Ethics Committee (MREC) of the Ministry of Health Malaysia (reference: NMRR-15-2200-27537). All participants have provided a signed consent form prior to the interview sessions.

The gatekeeper (primary care clinic) was approached by the researcher (AM), who has provided detailed information about the study. A list of potential participants from the diabetes registry that fulfilled the inclusion criteria was then prepared by the gatekeeper. A total of 40 invitation letters, patient information sheets and consent forms were sent to potential participants. They were then contacted by the researcher to confirm their willingness to take part, answer any questions, as well as to arrange the time and venue for the interviews. Interviews were held at venues which are convenient for the participants, such as at: workplaces; participants' homes; and coffee shops. Some of the interviews were carried out via telephone. The sample size was determined by data saturation, in which interviews were stopped once redundancy of information occurred, or when no new information was expected from the interview (Ritchie *et al.*, 2013). Figure 3.1 displays the flowchart of the procedure for this study.

An interview guide was developed based on the literature review (Chapter 2) and clinical experience as shown in Figure (13). Two pilot interviews were conducted using the translated interview guide, and minor changes to the terms used were made to allow for the interviewees to provide substantial and meaningful responses. The semi-structured interviews covered participants' experiences of being diagnosed, self-management support, or education sessions they have received, and their view on the current level of services available. Probing questions were used to gain detailed descriptions from the participants. All interviews were conducted face-to-face or by telephone, and later transcribed verbatim by the researcher (AM). All transcriptions were analysed in the language spoken, Malay, and selected quotes were then translated into English and checked by a translator to ensure accuracy.

Figure 13: Study procedure.

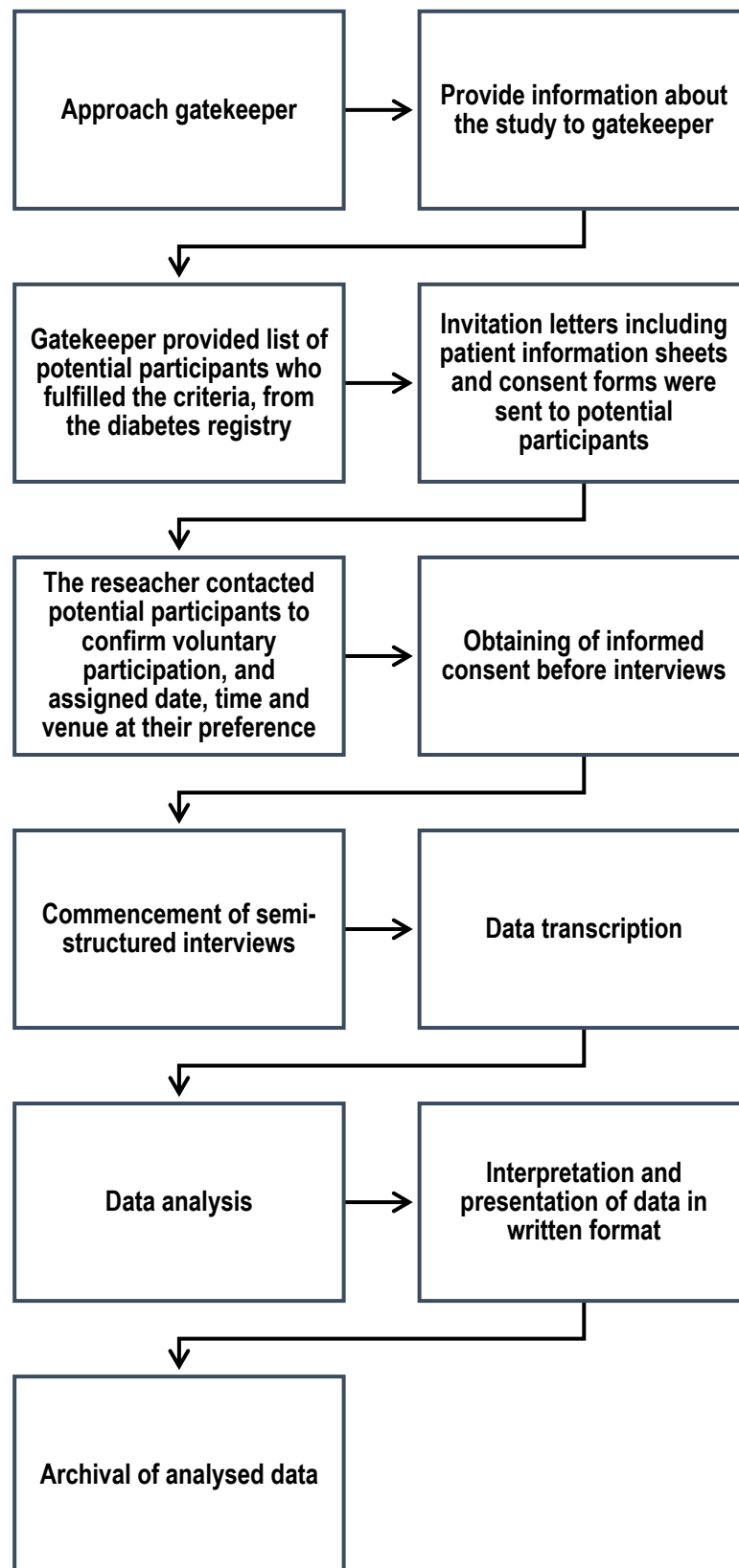


Figure 14: Interview topic guide.

Diagnosis

- When you heard the diagnosis, how did you feel at the time?
- How are you feeling now?

Self-management

- From your experience, what helps you in your daily diabetes care?
- And what makes it more difficult? Can you give me examples?
- What do you wish you have learned from your doctor, nurse and dietician? Please give me examples?
- What is your preferred health practices and beliefs in your diabetes care? Prompt: Conventional or complementary medicine
- Do you use home/folk remedies, shaman or spiritual healer in your diabetes care? If yes, why?

Support

- How important are the people around someone with diabetes in helping them to control their disease?
- From your opinion, who are the most important supporters for people with diabetes? And what kind of support and how have they supported you with your diabetes care?
- What is the best approach for diabetes educators to teach people with diabetes about diabetes? Prompt: the method of delivery; if you were invited for diabetes education class what are the topics you would like to discuss?

Services

- What diabetes services have you found helpful in Malaysia And what about in where you live?
- Are you aware of local diabetes support group? Do you participate? How does this support group help you with your diabetes management?
- Have you ever received counselling from a dietician? Where was that? How did that go?
- Have you been able to use any other community service or education or counselling session (guidelines, booklets, brochures, peer group activity) developed by any institution (association or ministry of health), to meet the specific needs of your condition? If so, please elaborate more with examples

3.4.4 Data analysis (The Framework method or analysis)

Data from the interviews were analysed by generating themes based on the thematic framework analysis approach in identifying, interpreting and reporting patterns of themes. All transcriptions were examined for accuracy by AM before they were imported into the qualitative software Nvivo version 11.0. For this study, themes were drawn inductively from the data where the coding process was based on the feedback from the participants and it is not abided to an epistemological or theoretical perspective.

The Framework method was adopted to summarise the data to answer the research questions and has many similarities to the thematic analysis especially at the earliest stage of analysis (Ritchie et al., 2013). The researcher independently chose to implement this type of qualitative analysis approach for a range of reasons. First, it is commonly used among qualitative healthcare research teams in analysing data from semi-structured interviews (Gale et al., 2013) where analysis performed cross-sectionally and the interpretations of participants' experiences are transparent.

Second, it is the approach of choice because of the type of data it produces from the semi-structured interview, and the framework analysis is not bound by any specific epistemological position, giving it the flexibility and 'best fit' the aims of this piece of research (Ritchie and Spencer, 1994). Ritchie & Spencer outlined the four types of research questions that may be addressed by the framework analysis as below:

- i. Contextual: Identifying the form and nature of what exists among the subjects.
- ii. Diagnostic: determining the reason for or cause of what exists among the subjects.

- iii. Evaluative: Appraising the effectiveness of what exists among the subjects.
- iv. Strategic: identifying new policies or plans of actions.

The research questions in this study (What are the life experiences regarding self-management for Malaysians who newly diagnosed with T2DM? and What are the challenges encountered by them in their daily diabetes self-management?) fitted both the contextual and diagnostic categories. The researcher is interested in further exploring the experiences of Malaysian adults who were newly diagnosed with T2DM in their diabetes self-management (contextual), along with the challenges they encounter to be able to self-manage their condition (diagnostic). Moreover, at a later stage of this thesis project (post the MY DEUMI intervention), the researcher has conducted exit interviews, asking some questions, which can be categorised as an evaluative category.

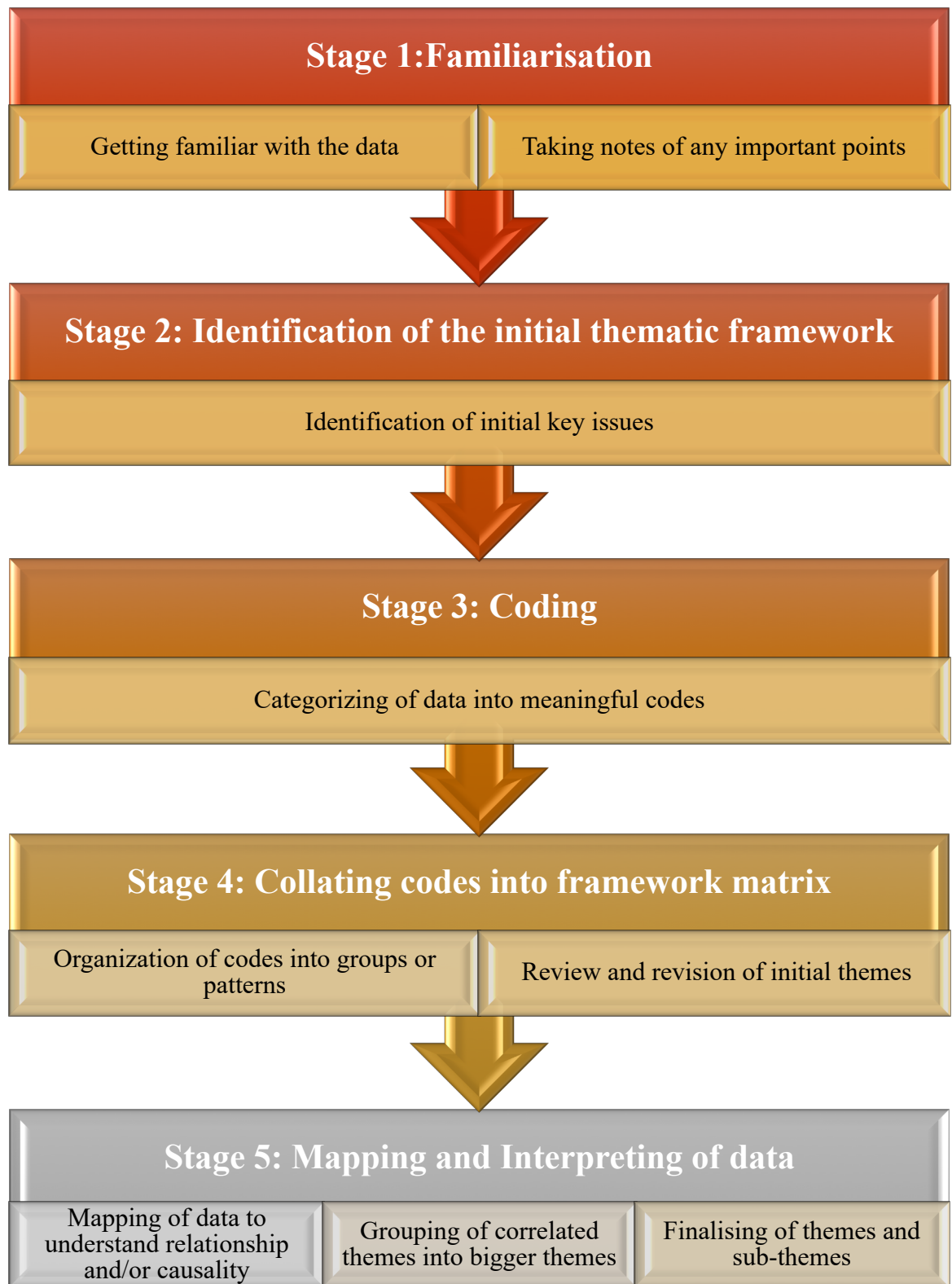
Besides, this method is highly suitable for this study where opinions and experiences of each participant are homogenous (data collected mainly covers similar topics as the discussion was focused on diabetes self-management) and it can be compared and contrasted. Unlike the grounded theory approach, the framework method is less focused on theory as the outcome of research and it is a practical method to address the specific research questions in this study. In addition to the above, in this study context, the researcher is interested in participants' personal life experiences regarding their diabetes self-management, which focuses more on the experiential rather than to the grounded theory, which is to understand the significant phenomenon at the specific time within specific situations experienced by the research participants (Creswell, 2014). Another approach which can be considered is the Interpretative Phenomenological Analysis (IPA) which is widely used in the clinical psychology study in the UK, to understand peoples' experience regarding particular condition (for

example what is it like to experience T2DM?) (Smith, Flower and Larkin, 2009). However, the core feature of the sample should share the same characteristics, but this study's age range of the respondents was large (range of age were from 26 to 66 years old).

Third, this valuable tool to analyse qualitative data fit for the researcher as an early career researcher (novice researcher) due to the explicit described processes as detailed in the next paragraphs. As a novice researcher, qualitative data management and analysis can be a daunting and complex task and this framework guide systematically from descriptive data (summarising and coded data) to an explanatory detail by the generated themes.

According to Ritchie, emerging themes can be identified after 5 key stages of analysis: (i) familiarisation of the data by reading through the transcripts before coding; (ii) identification of initial thematic framework; (iii) indexing using numerical or textual codes by AMM; (iv) charting of the data within the framework matrix using headings from the thematic framework; (iv) mapping and interpretation of data by searching for patterns, associations and concepts. These were finalised in a discussion (AM and KW), and a consensus was reached for the themes and sub-themes. See Figure (15) for the summary of the thematic analysis procedure. A detailed explanation of the five stages will be given in the following section.

Figure 15: Summary of the thematic analysis procedure.



Stage 1, Familiarisation:

A verbatim transcription using a good quality audio recording was obtained. Then AM listened to the audio-file to become familiar with and immerse in the data. Then, the transcription was read without taking note, to identify possible data patterns. In the second round of reading, notes on important points were made for the coding in the following stages.

Stage 2, Identification of Initial Thematic framework:

Following familiarisation with the data, some initial key issues and themes for further exploration were highlighted, while patterns and topics of interest were noted as potential themes.

Stage 3, Coding:

The transcript was read line by line, and notes were made using paraphrase or labels (a code) of potentially important themes. It is important to code anything that is potentially relevant at this stage, for example any particular behaviours, values, beliefs and emotions. This activity was systematically conducted with the aim of classifying the sets of data which could then be compared, and to give full and equal attention towards the entire data set.

Stage 4, Collating Codes into Framework Matrix:

The coding process allows for the data to be organised into meaningful codes. During this stage, the codes were charted into the framework matrix. The aim of the charting process is to summarise the data by categorising them from each transcript and developing them into themes. Interesting or meaningful quotations were included in the matrix chart. Mind maps were used to organise and understand the relationship between the themes that emerged from the codes.

Stage 5, Mapping and Interpretation of Data:

This involved reviewing and refining the themes. The themes were merged if fitted together and discarded if they were irrelevant, to enable the data to be divided into themes and sub-themes. The aim of this stage is to ensure that the themes captured all the information from all the codes, and a consensus from all the research members was achieved.

The researcher extracted significant excerpts that demonstrate the essence of each theme and sub-themes, to elaborate and answer the research questions.

3.5 Results

Forty participants were invited from 100 nominated individuals listed by the diabetes nurse in the primary care clinic from the diabetes registry. Potential participants were shortlisted by the researcher (AM) according to the inclusion criteria (type of diabetes, age and date of diagnosis), as well as the ratio of ethnicity in Malaysia 70:20:10 (Malay: Chinese: Indian). Seventeen participants with a recent diagnosis of T2DM (at least three years of diagnosis from the point of recruitment) were interviewed. Of the remaining invited participants 15 were unapproachable (the contact number in the registry was no longer in use), 7 expressed interest but declined due to work commitment (3 were doing shift work in Singapore, and 4 were working locally either shift work or office hours), and 2 housewives were interested but no suitable date was found because of their childcare commitments.

3.5.1 Sociodemographic characteristics of the participants

For this study, saturation was achieved by the 15th interview and the last two interviews were conducted to check for any other new information. The mean age was 48 ± 11.3 years (range 26-66 years), and the majority of the participants were females (60%). Fourteen participants were Malays, 1 was Chinese and 2 were of Indian ethnicity. The majority of the participants ($n=12$, 70%) were still working, 2 (12%) were retirees, and 3 (18%) were housewives. Ten (60%) had an immediate family with diabetes. Most of the participants ($n=15$, 90%) were prescribed at least one type of oral hypoglycaemic agent.

The interviews were conducted by AM at the participants' convenience: 3 at the workplaces; 5 at participants' homes; 2 at a coffee shop, and 7 were interviewed through the telephone. The mean duration of the interviews was 38 ± 11 minutes, in either Malay or English, depending on their preference. The main demographic characteristics of the participants are as listed in Table (3.1).

Table 3.1: Demographic characteristics of the participants (N=17).

Characteristics		Mean (SD) or n (%)
Age years (mean, SD)		48 \pm 11
Gender, n (%)	Female	10 (60)
	Male	7 (40)
Ethnicity, n (%)	Malay	14(80)
	Chinese	1 (8)
	Indian	2 (12)
Occupational status, n (%)	Working	12 (70)
	Retiree	2 (12)
	Housewife	3 (18)
With family history of T2DM, n (%)	Yes	10 (60)
	No	7 (40)

3.5.2 The overall perception on diabetes self-management

Participants generally (n=9; 53%) agreed on the importance of self-efficacy, where this is essential for people with T2DM to help them optimise their lifestyle, and to manage their condition effectively in addition to support from family members. However, there were barriers expressed by the participants and these barriers have brought complications to their diabetes self-management practices.

3.5.3 Participants' prior experiences of diabetes education

Four participants have previously attended diabetes education sessions at the primary care clinic, where 2 received a lecture by a nurse, and 2 have had individual consultations by a dietitian. Another 2 participants have been invited to diabetes education sessions but were not able to attend. Meanwhile, the majority (n=11; 65%) have never received any formal invitation to any diabetes education sessions. Three initial themes emerged from the data. These are: (i) psychological issues; (ii) social factors and culture; (iii) environment. Within each key theme, there are further sub-themes (Figure 16).

Figure 16: Main themes and sub-themes.

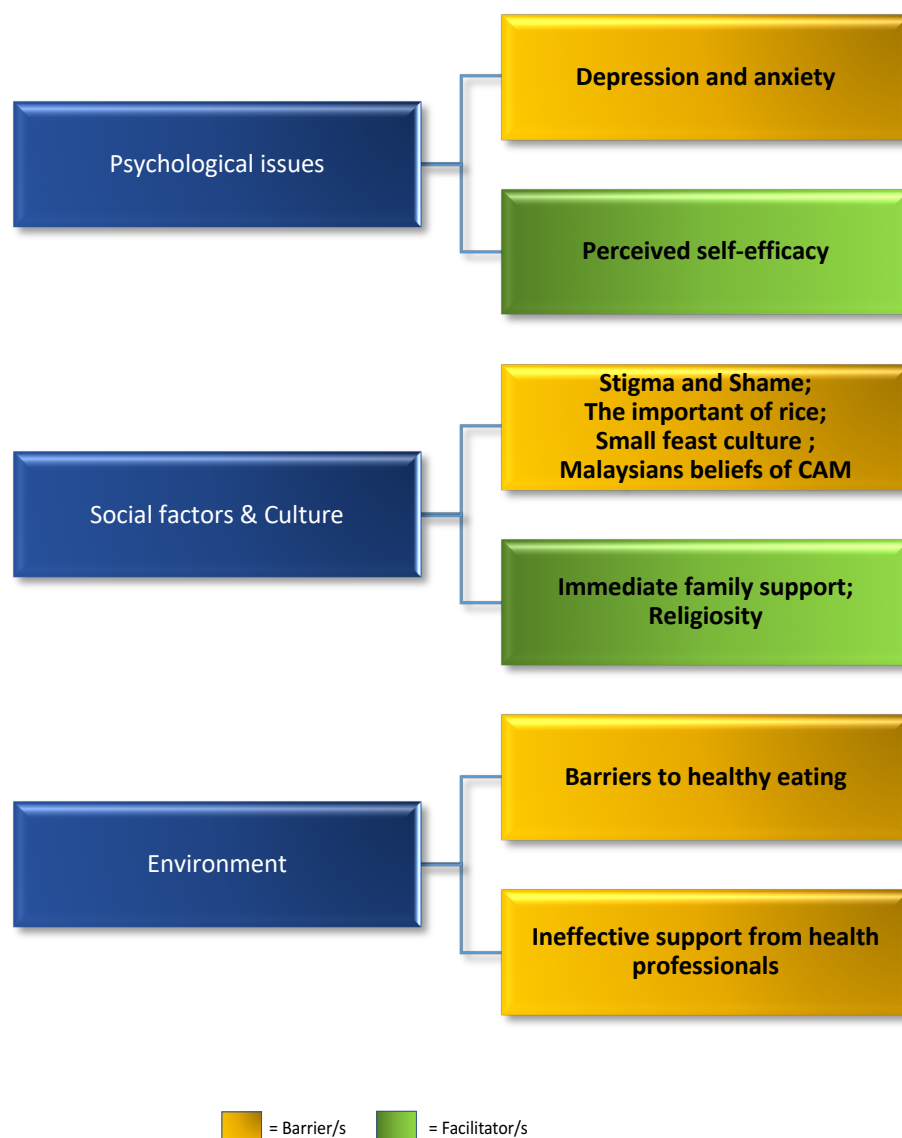


Table (3.2) illustrates all the main themes with further sub-themes, identified as facilitators and barriers to effective self-management with selected excerpts for further explanation.

Table 3.2: Barriers and facilitators in diabetes self-management expressed by people with newly diagnosed Type 2 diabetes (N=17).

Main Theme	Barriers/ Facilitator	Excerpt	N (%)
1	Psychological issues		
	Depression and anxiety	<i>"...I reckon for people with diabetes there is no hope to be happy like others. No more freedom for me..."</i> and <i>"I can see amputated people with diabetes around me and some with foul foot. I feel sad and worried thinking about it."</i>	10 (59) 12 (71)
	Perceived self-efficacy	<i>"It is hard. For example, the teh Tarik (tea with sweetened condensed milk), I always want to drink it, but it depends on you to change the habit [...] we must have the discipline and accept the fact that we have diabetes. That's it."</i>	9 (53)
2	Social factors		
	Stigma/shame	<i>"They said 'This is what happen when you always eat sugary food'. I have to agree with them but what they said have make me feel upset and hurt too."</i>	7 (41)
	Immediate family support	<i>"My wife is the most important person in my diabetes management."</i>	11 (65)
	Culture		
	The importance of rice	<i>"We are Malaysian. We eat rice since we were born. Oh, my! Out of a sudden, we can't eat that much."</i>	7 (41)
	Small feast culture	<i>"There will always be wedding ceremonies, small feasts, parties and the list goes on, and you know they serve biryani, sweet and savoury snacks, as well as cookies. It is very challenging."</i>	3 (18)
	Malaysians beliefs of CAM	<i>"I take traditional medicine secretly because I feel that traditional medicine is part of our effort too."</i>	11 (65)
	Religiosity	<i>"We have to put an effort and then leave everything in God's hands."</i>	5 (30)
3	Environment		
	Barriers to healthy eating	<i>"During feast invitation, we can't eat all the food served (non-diabetic meal). How are we going to deal with that?"</i>	7 (41)
	Ineffective support from healthcare providers	<i>"We've been waiting for so long for our turn during the follow-up, and end up getting scolded. The doctors, they only know how to tell you off, if the blood result is not good."</i>	9 (53)

3.5.4 Main Theme 1: Psychological Issues.

For the first main theme, which is the psychological issues, 2 sub-themes have been identified as affecting diabetes self-management. The first is a potential barrier, depression and anxiety, which were identified when exploring participants' feelings about having T2DM at diagnosis and at present. While the second sub-theme is a facilitator, which is perceived self-efficacy.

Depression and anxiety

Of the 17 interviews, ten participants (60%) reported feeling depressed at diagnosis, while 12 participants (70%) expressed feeling anxiety regarding the disease or the complications experienced by them or surrounding people. Participants found it difficult for them to accept that they were diagnosed with T2DM, and having to live with the condition until the end of their life; a negative emotion that is affecting their day-to-day lives.

“I feel terrible and worried because none of my siblings is diagnosed with diabetes. So, I thought that I wouldn't have it.” (R4, female, aged 56).

“Ermm for me... you cannot cure this disease. This sickness will demotivate a person's spirit [...] Ya! I reckon for people with diabetes there is no hope to be happy and cheerful like others. No more freedom for me and that is not the best feeling.” (R16, female, aged 42).

Apart from that, feeling depressed at some point following the diagnosis, the participants in this study also admitted feeling anxious and worried about the complexity of diabetes treatment. For example, insulin injection or the complications that they might face in future.

“I don’t like hearing about insulin. If possible, let me only swallow the medicine.” (R6, male, aged 66).

“I’ve been thinking all this while if I cut myself unintentionally, is that going to heal or not?” (R16, female, aged 42).

Furthermore, participants also identified that complications experienced by their relatives and friends are a significant trigger for anxiety.

“Erm, the doctor told me that I might end up with dialysis. Errmm, my late husband [he] used to undergo dialysis and surely I don’t want to end up like him.” (R8, female, aged 63).

“I used to cry when I saw amputated people with diabetes around me. I feel sad and worried just thinking about it.” (R17, female, aged 41).

Perceived self-efficacy

Despite the anxiety and depression experienced by the participants, a facilitator of good diabetes self-management has also been identified. Perceived self-efficacy was expressed by half of the participants. Many expressed how perceived self-efficacy has helped them to take control of their disease management, and encouraged them to have a positive attitude towards their diabetes self-management.

“It is hard to manage diabetes. For example, the teh tarik (tea with sweetened condensed milk) I’m always craving for it, but basically, it depends on your will to change the habit [...] we should be more disciplined and fully accept that we have diabetes. That’s all.” (R1, male, aged 57).

“Sometimes we need to look at the ingredients because some of them (pre-prepared food) are high in sugar” (R2, female, aged 56).

“Basically, it is about knowledge. I’ve become motivated through my readings....” (R11, male, aged 45).

“First thing first is self-awareness. Once you are a diabetes patient that’s the fate of your life and you need to do something to reduce the symptoms and effects.” (R12, male, aged 33).

“If (I am) attending any feast or party I have no problem to eat. I will choose and eat more vegetables [...] but my husband like to bring me out for midnight supper, so I’ll accompany him and choose healthy simple snacks.” (R16, female, aged 42).

3.5.5 Main Theme 2: Social factors and Culture

Social factors

Social factors play a role in influencing thoughts, perceptions and behaviour in a community. The experiences faced by the participants do have some negative consequences for their diabetes self-management. The main social barrier identified were stigma and shame. On the other hand, immediate family support was a facilitator towards good self-management. Support received from family members has helped the participants to balance the pressures encountered, as well as increased their motivation and self-efficacy for diabetes self-management.

Stigma and Shame

Some of the middle-aged working adults with T2DM faced difficulty following a diabetes diet on a daily basis because of stigmatisation. They felt distressed about this and wanted to be accepted as ordinary people in the community.

“Sometimes they (friends) tease me ‘What’s up! Not taking any sugar?’ in the restaurant. Some of them were confused when I ordered tea without sugar and said, “Ehh! how do you (manage to) drink tea without sugar?” (R11, male, aged 45).

“At small feasts, the common dialogue was “Hah! You can’t eat this and that; Remember! That you have diabetes” I feel dishonoured” (R16, female, aged 42).

One participant shared his concern about how the community reacts to people with amputations because of diabetes.

“If our leg or hand is amputated you know how the community will react. If the condition worsens (infected diabetes foot ulcer), no one will want to be next to us. They are disgusted.” (R6, male, aged 66).

Participants stated that many people consider diabetes is only diagnosed amongst older adults and this makes them feel ashamed.

“I feel ashamed. I am still young. I’m in my 30’s. It is embarrassing when our office mates tell others about my disease. Why do they have to tell others? It is embarrassing.” (R7, female, aged 36).

“Once I declared myself diagnosed with diabetes most of them were shocked. So, I explained to people about the nature of this disease. In my community, many of them are shocked when they find out that I have diabetes.” (R12, male, aged 33).

Immediate family support

Eleven participants explicitly reported that they valued the attention given by family members in their daily lives. These statements demonstrate how important it is for them to have this focussed support with their diabetes management.

“My wife is the most important person in supporting my diabetes management, in terms of moral and also physical support, such as diet and medication.” (R1, male, aged 57).

“My husband...he always reminds me of everything such as diet, medicine and clinic appointments.” (R7, female, aged 36).

“My late husband. He was a very strong (motivated) and a supportive man, and he didn't want me to end up like him (diabetes nephropathy underwent dialysis on alternate days). He kept me strong and always reminded me of my medicine and medical appointments.” (R8, female, aged 63).

“Family is significant to me especially my close family. In my case, my wife always reminds me to take my insulin injection before work.” (R12, male, aged 33).

Culture

Culture is a strong determinant of health-related behaviour, and can be transmitted through generations with strong values, and accepted as norms in the community. Culture was found to be a particular sub-theme, and 3 challenges have been identified among the participants: (1) the importance of rice; (2) the small feast culture; and (3) Malaysians' beliefs in herbal medicine. Whereas one facilitator of diabetes self-management has also been identified and that was religiosity.

The Importance of Rice

The necessity of rice intake among Malaysians was cited as a reason for poor glycaemic control. Participants understood the need for a change in their rice intake to reduce the glycaemic effect, but were often not ready or reluctant to change their behaviour.

“Talking about rice, we Malaysian Malays we won’t get full without eating rice.” (R1, male, aged 57).

“We have to eat rice if not we feel weak. It’s already programmed in our brain...hahahahha!..rice is a must!” (R12, male, aged 33).

“We have a Malay tummy, don’t we? If we go 2 or 3 days without rice, we’ll shake in our knees. Hahahahha...” (R14, female, aged 27).

“We are Malaysians. From small, we eat rice. Oh, my! All of a sudden, we can’t eat that much.” (R17, female, aged 41).

Small feast culture

Participants felt that the small feast or treat culture among Malays could be an attribute to their failure in following the diet recommended by healthcare providers.

“There will always be wedding ceremonies, small feasts, parties and the list go on, and you know they serve biryani, sweet and savoury snacks, as well as cookies. It is very challenging.” (R2, female, aged 56).

“This is our culture. So many feasts and festivities throughout the year.” (R17, female, aged 41).

“We do serve a lot of high-fat food, sweet and savoury snacks, cookies and many more during festivals and small feasts.” (R4, female, aged 56).

There was also a concern in refusing the meals served at any small feast ceremonies amongst the Malay community. This non-assertiveness, reserved, and pleasant attitude are claimed to come from the Malay cultural values.

“This is our culture, and we don’t want to hurt other people’s feelings. People would say you are arrogant if you do not eat the meal served at the small feast or party.” (R16, female, 42).

“In our culture, they will serve you and give you a full plate of food. One of the biggest barriers for me is, it is like a sin if we do not eat the meal served to us.” (R17, female, aged 41).

Malaysians’ belief in herbal medicine

Despite receiving and consuming prescribed medication, many of the participants also have a strong belief that herbal medicines could help them manage their blood glucose level. Belief such as this may complicate medical management, and put people at risk of side-effects.

“We take extra supplements to help us cope with it (diabetes) [...] we can’t just depend on the drugs (we get from the doctor).” (R1, male, aged 57).

“Now, I drink Pxxxxx (a traditionally prepared liquid health supplement) and it helps me. I feel much better, have less numbness, and my breathing is getting better than before. I feel more energetic than before, and I’ve consumed it for the last three months.” (R2, female, aged 56).

“I take traditional medicine secretly because I feel that traditional medicine is part of our efforts too. I do eat bitter local vegetables regularly in the form of juice such as bitter melon or the noni fruit with green apples.” (R3, male, aged 52).

“I never left the modern medicine, and traditional medicine is a just supplement that helps. I do eat a lot of bitter melon as salad, as well as Sabba grass leaves juices and dried sky fruits in capsules.” (R11, male, aged 45).

“I do drink a traditional Chinese herb medicine regularly in the form of tea.” (R13, female, aged 46).

Religiosity

Some of the participants in this study appeared to accept the diagnosis of diabetes without reservation. Malaysians are renowned for being a nation with strong religious values, and many participants highlighted the importance of spirituality in reducing their anxieties and boosting their self-confidence. Therefore, religious belief may promote diabetes self-management for some individuals.

“We have to be more disciplined in our diabetes care. We should accept the fact and wholeheartedly agree to our fate from the Almighty that we’ve been diagnosed with diabetes mellitus.” (R1, male, aged 57).

“What we can do, is just leave it to the Almighty after trying and looking after of our body.” (R2, female, aged 56).

“We follow doctors’ advice and take the medicines. For our health, we must pray to the Almighty.” (R6, male, aged 66).

“We will face this situation (complications) because we already have this disease. It is permanent. We should put in an effort to manage it and then leave everything in God’s hands.” (R7, female, aged 36).

“We Muslims, we have to work hard to find solutions and pray to the Almighty,” (R11, male, aged 45).

3.5.6 Main Theme 3: Environment

This theme expresses participants’ view of how some environmental factors may negatively impact their efforts to change their lifestyle, and to control their blood glucose level. Two environmental barriers to this theme are; (1) difficulties with diet management, and (2) ineffective support from healthcare providers.

Barriers to healthy eating

Participants expressed frustration about the unsupportive environment towards lifestyle change, in particular, dietary management.

“We are living in the city, have a look at our surrounding environment. Now, every day I can eat flatbread 24 hours 7 days a week, it’s not like in the 60s.” (R6, male, aged 66).

“When we get thirsty while working, what type of drinks do you see inside the fridges in Malaysian shops? It’s all full of carbonated drinks and juices.” (R11, male, aged 45).

“We are full-time working parents, and sometimes it’s hard to cook every day so, we need to eat at stalls or takeaways. Outside and takeaways foods, if it is sweet, it will be extra sweet. So far, I couldn’t find any diabetes-friendly restaurants or food stalls. Ermm how I wish for a diabetes-friendly food stalls.” (R12, male, aged 33).

Apart from the problems accessing healthy fast food, two participants reported that the traditional dishes served during feasts and festivals are not suitable for people with diabetes. This have made it difficult for them to enjoy social activities with people who do not have diabetes.

“It is distressing, for example, none of the wedding ceremonies that we attended have food for diabetes. It's all high in fat and carbs.”(R16, female, 42).

“Let’s think back during the festive season. We’ll visit all our relatives and friends, up to 5 houses a day. We can’t eat all the food served. How are we going to deal with that?” (R17, female, aged 41).

Ineffective support from health professionals

Another environmental barrier was the lack of support from diabetes services. Most participants shared unpleasant experiences with health care professionals at the primary care clinic and felt intimidated by the non-constructive feedbacks and criticisms.

“We’ve been waiting for so long for our appointment, and ended up getting scolded. The doctors, they only know how to tell you off if the blood result is not good.” (R7, female, aged 36).

“They (doctors) must give us more supportive feedback. For example, in my own experience, my question was “How dangerous is diabetes?” The answer was “Have you see people with amputations (using layman and harsh word)? If you want to end up like them, then don’t take your medicine and care for your diabetes.” Can you imagine how I felt at that moment?” (R9, male, aged 58).

“During the education session, the information given was the same for all whether you are working or a housewife. They (health care professionals) should help us manage our diet depending on our daily working routine because we have different needs.” (R11, male, aged 45).

“I have had few experiences with a nurse giving me some advice in a very unprofessional way that makes me feel disheartened to go for my appointments.” (R12, male, aged 33).

3.6 Discussion

The purpose of this study is to explore the experiences of Malaysians newly diagnosed with T2DM, in an attempt to understand the challenges for their diabetes self-management. Apart from that, the existing Western evidence or model may not be fully applicable to people of Malaysia, and this study may give us a better understanding of their needs, and help to identify the factors that may promote behavioural change. During the semi-structured interviews, the participants responded to questions about their diagnosis, self-management, support and experience of services. The findings suggest both barriers and facilitators of effective diabetes self-management, while eliciting useful information to inform the development of the MY DEUMI intervention. Results from this study suggested that barriers and facilitators of self-management among people newly diagnosed with T2DM in Malaysia can be divided into three main themes: (i) Psychological issues; (ii) Social factors and culture; and (iii) Environment.

Our study revealed that there are psychological issues acknowledged by Malaysians with T2DM, and most participants reported experiencing at least one emotional disturbance either at the point of diagnosis or around the time of interview. To our knowledge, these are new findings from the Malaysian patients' perspective, and the participants interviewed were middle-aged adults with diabetes. In accordance with literature, previous cross-sectional prevalence studies in Australia, aimed to understand the correlation of depression and anxiety, have shown that these issues were more prevalent in middle-aged adults compared to older adults (Poulsen and Pachana, 2012; Browne, Scibilia and Speight, 2013). Psychological support should be considered relevant in this population to reduce complications resulting from poor self-management and improve quality of life. This is supported by a meta-analysis that

revealed that there is an association between depression and diabetes complications (de Groot *et al.*, 2001). Furthermore, a systematic review and meta-analysis of RCTs of psychological diabetes interventions demonstrated that people who received this type of intervention have better control of their psychological distress (Ismail, Winkley and Rabe-Hesketh, 2004). A more recent systematic review and meta-analysis of 14 RCTs on psychological treatment or pharmacotherapy for people with diabetes who were depressed, demonstrated that a collaborative care has a greater effect on depression and glycaemic control (Feltz-cornelis *et al.*, 2010).

Within the context of this study and thesis, there are a number of subthemes that emerged concerning social factors and culture. Results from this study revealed that experiences of social stigma in the community or work settings were cited as being particularly disruptive. This is comparable with the wider research literature. For example, a qualitative study in Singapore among working adults in the outpatient clinic of a specialist hospital where half of the participants claimed that workplace stigmatisation affected their diabetes self-care (Lee, Lim and Koh, 2015). Furthermore, a recent online survey conducted in the US (N=5,422) to determine the psychosocial impact of diabetes stigma (both type 1 and type 2) indicated that the common form of diabetes stigma experience was the blame and shame (~80%; type 1, n= 1334; type 2, n=3833) (Liu *et al.*, 2017). The respondents claimed that their community blamed them for being irresponsible with their health, and this affected their emotional well-being, and was statistically significantly associated with uncontrolled diabetes (HbA1c > 7% or 53mmol/mol and BMI > 25kg/m²).

While social stigma is a problem for participants in this study, this research demonstrates that there is a specific cultural context of living with T2DM in Malaysia which needs to be addressed. It is important that this is considered in future diabetes interventions to increase confidence and self-efficacy in diabetes self-care for local people. For example, the importance of eating rice and following the eating patterns that have existed since childhood. Next, is the small feast culture, which appears to be one of the most significant barriers in maintaining the desired glucose level. This infrequently happens among the Westerners, where meals are usually only offered for close friends/family and respected guests (Douglas, 1975). Our findings are aligned with an ethnographic study among the Middle Eastern people in the United Arab Emirates (UAE), which demonstrated that providing meals to strangers, guests and friends, is a way to minimise social gap and to honour their presence (Baglar, 2013). Eating food served in order to be polite is part of the Malay culture, and this can hinder efforts of dietary modification.

Furthermore, our findings suggest that CAM use is culturally acceptable. Therefore, more information regarding the safe practice of CAM among the public in Malaysia, and specifically to people with T2DM needs some consideration. A literature review of the Malaysian healthcare system reported that CAM is widely used among the local people, to maintain general health and well-being, and it was concluded that more research are required to improve regulations and standards among practitioners (Raja Rina and Mohd Khanapi, 2015). The CAM has always been available alongside conventional medicine. For example, a local cross-sectional study on the usage of complementary medicine among Malaysian community (N=6947) reported that the highest (88.9%) CAM used by participants in this study was mainly herbal medicines (Siti *et al.*, 2009). The main reasons given for CAM usage among

participants in this study is to complement conventional therapy and aid general diabetes self-management. These findings are in agreement with a further survey among 205 people with a chronic disease, which demonstrated that Malaysians prefer to combine the prescribed medicine with traditional medicine (Hasan *et al.*, 2009). In other countries, especially those where people may have limited access to conventional medicine, such as in South Africa, the use of CAM is widespread (Singh, Raidoo and Harries, 2004), while in Tanzania, complementary medicine is well-established and sophisticated as well as cheaper than the conventional medicine (private health care system), making people with diabetes attempt to try it at least once for their disease management (Kolling, Winkley and von Deden, 2010), and in Uganda, the CAM is used after perceived failure of conventional medicine, (Hjelm and Atwine, 2011).

Aside from the psychological, cultural and social factors, the unsupportive built environment (human-made surroundings such as infrastructure and available resources and services) and social environment (physical and social setting including the learned culture) were also reported as a barrier. Diabetes prevention campaigns to promote diabetes-friendly meals to the public and food providers through respective governmental agencies may support people with T2DM or at risk of T2DM. In the current study, participants felt unable to adhere to dietary modifications due to the limited choice of healthy food available during working hours at an affordable price. Moreover, the inherited style of cooking among Malaysians such as deep-frying, creamy coconut milk (curries) dishes, as well as the sweet and savoury treats, are cheap and available 24 hours. A recent literature review regarding sugar consumption among Malaysians revealed that there is a high content of sugar added to food, and 10% more than the total calories recommended by the WHO (Amarra, Khor and Chan,

2016). Healthier cooking and education regarding food choices should be promoted and facilitated by health professionals to ensure people with T2DM adhere to nutritional recommendations to improve their diabetes control. Apart from that, diet modification should consider cultural preferences to increase sustainability among people with T2DM. This is supported by qualitative studies of immigrants in the western countries, which suggested that interventions with specific cultural adaptation may promote better diabetes self-management (Barko *et al.*, 2011; Cha *et al.*, 2012).

This study also identified that religion plays a role as a facilitator towards good self-care. The strong Islamic faith among our participants strengthened their motivation to adhere to their treatment. Islamic faith emphasises on the importance of leading a healthy lifestyle. Verses from the Quran and Hadith are central references to guide the way of life for Muslims before leaving it to God's will (Assad, Niazi and Assad, 2013). However, there is some literature that contradicts this study. Some report a fatalistic attitude that diabetes diagnosis is God's will, and is associated with poor diabetes control. A qualitative meta-synthesis conducted among ethnic minorities in developed countries to explore their experience regarding diabetes self-management demonstrated that fatalism is one of the main factors associated with a sense of powerlessness amongst people having difficulties to managing their diabetes (Jones and Crowe, 2017).

3.7 Strength and limitation of the study

This study's strength lies in its focus on people recently diagnosed with diabetes. Exploring their perspective provides vital information about their experience and needs with regard to diabetes self-management that contributes to a better understanding of the local community. The qualitative method allowed for the discovery of in-depth knowledge to understand the challenges faced by people with diabetes from different views, related to age and working status. More research is needed to explore the severity of these barriers so that the information can be used to improve disease management and national diabetes education programmes.

However, the limitation of this study is that only the views of people with diabetes were explored. Healthcare professionals' perspectives would have been beneficial to provide more information on the current service provision to support diabetes self-management for the local communities. Apart from that, the recruited participants that formed our sample are not representative of all the main ethnics in Malaysia. Therefore, further investigation is needed to see whether there are different barriers faced by other ethnic groups such as the Chinese and Indians.

Further limitations include the presence of interviewer bias as the knowledge and clinical experience of that the researcher has might affect the interpretation and analysis of the data. However, reflexivity, which is the social nature of an interview process, may reduce the effect of anticipated bias. This was countered by thinking reflexively (self-reflection by the researcher) throughout the research process, and during the analysis to reduce the chances of misleading the interpretation of the data by the personal and clinical experiences of the researcher (Patnaik, 2016).

Moreover, the involvement of the researcher's supervisor (KW) during the analysis process allows for a wider interpretation of the data. On the other hand, the semi-structured interview approach reduces the risk of disclosure of personal information or experiences during the interview process that may mislead the discussion (Sears and Rowe, 2003).

3.8 Implications for the MY DEUMI intervention development

The findings from the semi-structured interviews are of significance for the development of the MY DEUMI diabetes educational intervention, particularly, regarding how the intervention is to be delivered and what content should be included.

One main finding from this qualitative study is that the participants perceived they required psychological support. This underlines the importance of considering the most effective method to support psychological needs when developing diabetes educational intervention.

Another explicit finding is that participants claimed that cultural barriers to self-management included rice intake, feast culture and beliefs in complementary medicine. Therefore, to strengthen the self-efficacy among Malaysians with T2DM, in order to assist them in optimising their diabetes self-management using the available and culturally acceptable resources, may help to overcome the barriers. Furthermore, religious support may also be useful for some people, and could be considered in diabetes education programmes to increase motivation for behavioural change.

3.9 Conclusions

This study demonstrated that many barriers faced by Malaysian adults with T2DM in diabetes self-management are related to psychosocial issues such as depression, anxiety, stigma, environment and culture. The findings from this study may inform healthcare professionals working with people with T2DM within Malaysian context, and highlight specific requirements that could be addressed in diabetes consultations. Interventions should empower people with T2DM with coping skills to counter social stigmatisation and enhance their self-confidence.

It was also noted that there is a preference to combine conventional and traditional medicine amongst the people interviewed in this study. This suggests that more clinical research is needed if we are to identify whether these common herbal medicines used by Malaysians with T2DM are safe. It may be beneficial for people with diabetes to have access to educational material to promote safety. Consequently, Malaysians with diabetes may be more willing to discuss their self-care strategies and reduce the side effects of the abusive usage of CAM. The analysis also indicate the importance of support systems in optimising diabetes self-management, and if diabetes self-management education is to meet people's needs, it should involve the family to improve self-efficacy. The importance of religious beliefs should also be considered.

3.10 Summary

The views and experiences shared by the participants indicated that effective diabetes education intervention is needed to support diabetes self-management. Educational interventions should take into consideration barriers such as: (i) psychological issues; (ii) social factors such as stigma and shame, as well as specific cultural barriers to lifestyle change, such as the importance of rice and the small feast culture; and (iii) the unsupportive environment to self-management when people live with T2DM in Malaysia. Facilitators of diabetes self-management revealed that family involvement and religiosity might be useful.

The development of the MY DEUMI intervention should integrate findings from this study as well as consider the evidence from the systematic review (Chapter 2). In addition, other theoretical concepts and existing resources may be useful, therefore using all of these components, the next chapter discusses the process of developing the MY DEUMI intervention.

Chapter 4 : The Development Process of the *Malaysian Diabetes Education Intervention using Motivational Interviewing (MY DEUMI)* for people newly diagnosed with type 2 diabetes mellitus.

4.1 Chapter scope

This chapter describes the development of the MY DEUMI intervention, which integrates findings from the earlier chapters, systematic review (Chapter 2) and qualitative study (Chapter 3). It also presents a scoping study to identify relevant resources and the theoretical framework, which under-pins the MY DEUMI intervention. There are 3 sections in this chapter. The first section discusses the outcomes of the systematic review and qualitative study. The second section provides the details of the scoping study conducted, and the final section describes the diabetes guidelines as well as the theoretical framework used. Details regarding the chosen delivery method (motivational interviewing) are also included.

4.2 Introduction

The overall aim of the thesis is to develop a DSME intervention specifically for people who are newly diagnosed with T2DM in Malaysia. This study was divided into three phases. Phase 1 consists of the systematic review and qualitative study discussed earlier in Chapter 2 and 3. This chapter presents Phase 2 of the study, the development of the MY DEUMI intervention manual (written curriculum) by compiling findings from Phase 1.

The first three chapters of this thesis have summarised the pathophysiology explanation of T2DM and its management, the importance of DSME, the current literature and a qualitative study of Malaysians recently diagnosed with T2DM. They demonstrated that there is a need for DSME intervention tailored to the specific needs of people with T2DM in Malaysia which has a unique multicultural community with different health-care factors compared to developed countries. Criteria were set by the researcher based on current literature (Gamble *et al.*, 2017; Odgers-Jewell, Ball, *et al.*, 2017; Odgers-Jewell, Isenring, *et al.*, 2017) to determine what would be required for the DSME intervention as shown in Figure (4.1).

Figure 17: Criteria for a T2DM structured education to be adopted in Malaysia.

- The DSME intervention needs to be evidence based
- Delivery approach to enhance self-efficacy
- Uses a written curriculum for educators to follow
- The structure and content of the written curriculum aims to provide participants with information regarding T2DM and support their self-management
- Time management that could increase the effectiveness of the delivery and is acceptable to the participants
- Culturally appropriate or flexible to suit the multiracial and multicultural people of Malaysia

4.3 The MY DEUMI intervention development process

This thesis discusses the burden of T2DM in Malaysia, and the importance of DSME in promoting effective diabetes self-management to improve glycaemic control. It summarises some of the main DSME or DSE programmes available in the Western countries, and the positive impact on glycaemic control, as well as the various types and approaches to promote good diabetes self-management.

In order to examine the current evidence-based DSMEs among people with T2DM, a systematic review has been carried out and presented in Chapter 2. Results of this suggested the following components may be useful for the MY DEUMI intervention:

- group-based/facilitated mode of delivery
- intervention to consist of at least a total of 10 hours of contact
- to include hands-on activities

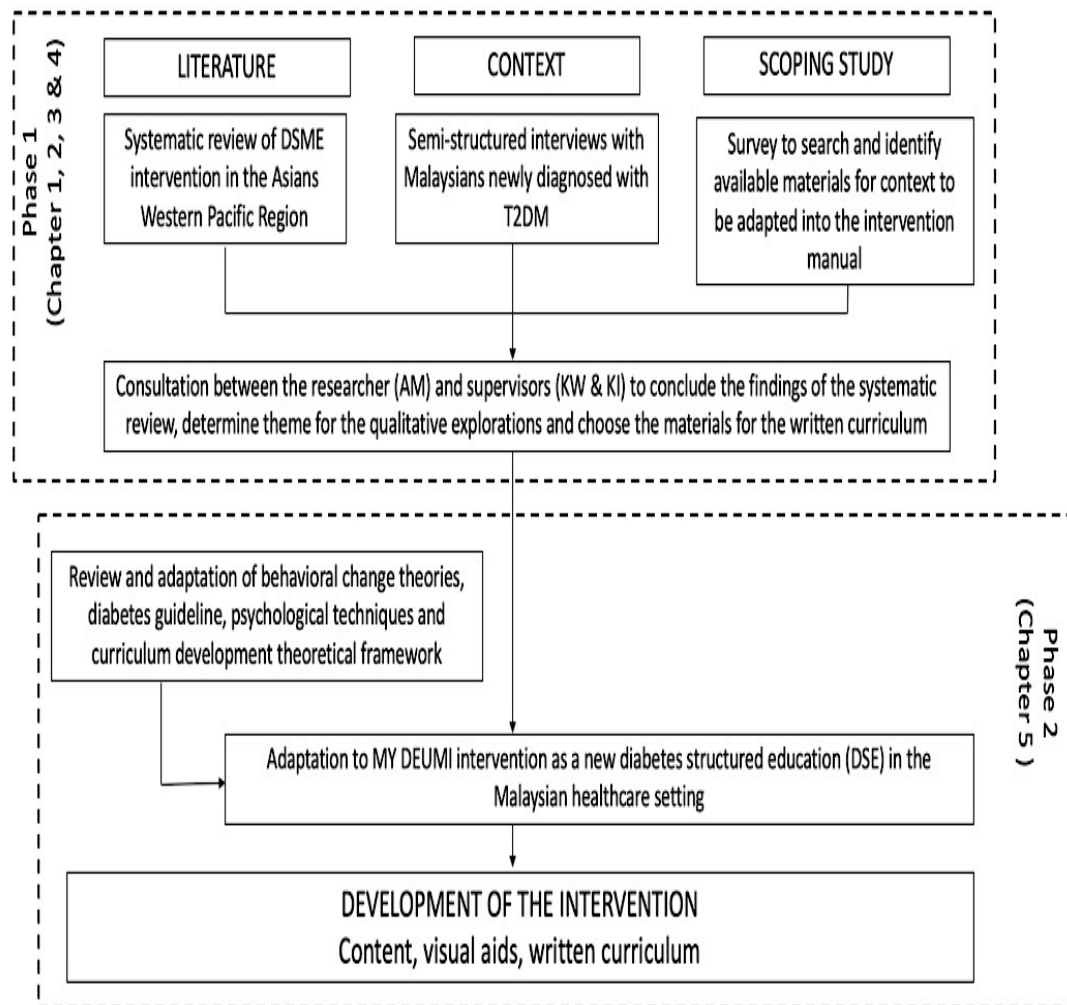
As the contextual nature of DSME intervention generally relates to the target group, there is a call for supplementary evidence regarding the needs of people with T2DM in Malaysia to optimise their lifestyle changes to achieve good glycaemic control; a qualitative interview study was then conducted (Chapter 3). The findings from the semi-structured interviews relevant for the development of MY DEUMI diabetes educational intervention include:

- Participants perceived they required psychological support. Therefore, stress management skills as part of the content, and Motivational Interviewing as the delivery approach may encourage personal resolutions and inspire potential participants to decide on the best options in their diabetes self-management especially with lifestyle modifications.

- Participants claimed that cultural practices such as rice intake, feast culture and beliefs in complementary medicine were among the barriers to their diabetes management. Therefore, most of the content in the manual of the intervention (MY DEUMI) are from local references, especially in the inputs for diet and information regarding complementary medicine.
- Malaysians are known as a community that value and practice their traditions and culture, therefore, reflection and discussion using the Motivational Interviewing techniques during the delivery process to address their concern and empower them to be more assertive in their choices are crucial.

To summarise, the preliminary intervention development procedure entails an integration of 3 components: (i) the outcomes of a systematic review; (ii) findings from the semi-structured interviews among Malaysians newly diagnosed with T2DM; and (iii) scoping of the available educational materials, which will be discussed in the next sub-topic. Additionally, DSME and SDE guidelines were considered, and behavioural theories as well as a curriculum development theoretical framework (outcome-based education (OBE)) have guided the development of the MY DEUMI intervention manual. The intervention development process is shown in Figure (18).

Figure 18: Integration of literature, qualitative exploration and scoping exercise for developing the MY DEUMI intervention.



4.4 The scoping study for written curriculum content

The objective of the scoping study is to synthesise relevant content from existing programmes such as those already offered in the United Kingdom, for instance the Diabetes education and self-management for ongoing and newly diagnosed (DESMOND), and a research intervention employing psychological techniques. The latter is a multi-centre randomised controlled trial comparing the effectiveness of enhanced motivational interviewing intervention (MOVE-IT) with usual care for reducing cardiovascular risk. This exercise also aims to map the range and types of available resources for diabetes education in Malaysia and identify those that could be used in the current intervention.

4.4.1 Complex structured diabetes education (SDE) or psychoeducational intervention in the United Kingdom (UK)

Diabetes education and self-management for ongoing and newly diagnosed (DESMOND)

DESMOND is a practical interactive and collaborative group structured education programme designed for people newly diagnosed with T2DM to support lifestyle modification and improve biomedical outcomes (Davies *et al.*, 2008; Khunti *et al.*, 2012). There are six self-management programmes available as shown in Figure (4.3).

All the programmes are evidence-based with toolkits (such as A safer Ramadan and Injectable therapies), available for any institution or individual to purchase. The programme has successfully expanded to Australia and New Zealand. One of the programmes DESMOND Newly Diagnosed, was observed by the researcher. Table (4.1) below summarises the characteristics of the programme. This trialled and evidence-based programme is supported by dedicated facilitators, has

adult learning theories embedded within it, and uses an interactive delivery style. Therefore, the DESMOND programme has been a useful starting point to consider, and has given some input to the development of the MY DEUMI manual intervention

Figure 19: List of DESMOND programme.

1. DESMOND Newly Diagnosed.
2. DESMOND Foundation (for those with established diabetes).
3. DESMOND Black and Minority Ethnic (cultural adaptation).
4. Walking Away from Diabetes (for those at high risk of developing T2DM).
5. Going Forward with Diabetes (the follow-on for those attended the newly diagnosed or foundation course).
6. Let's Prevent Diabetes.

Table 4.1: Characteristics of the Diabetes education and self-management (DESMOND) programme for ongoing and newly diagnosed participants.

Criteria	Characteristics
Target audience	<ul style="list-style-type: none"> ▪ Specific for an individual that has been diagnosed for a period of no longer than a year. ▪ Non-insulin pharmacological management of diabetes. ▪ Partner or friend is welcome to join the session for support.
Structure	<ul style="list-style-type: none"> ▪ Six (6) hours of structured self-management group education in a one (1) day or a (2) two half-day sessions, and open for partner or friend to take part. ▪ Delivered by two trained healthcare professionals, either in the health-care settings or local community facilities. ▪ The programme is offered monthly throughout the year. Saturday courses are available in certain health-care settings, to accommodate participants who are unable to attend on weekdays.
Content	<ul style="list-style-type: none"> ▪ Thoughts and feelings of the participants regarding the program: <ul style="list-style-type: none"> • An understanding of diabetes and glucose regulation in the body • An understanding the risk factors and complications associated with diabetes • A better understanding on monitoring and medication • How to self-manage T2DM – Food Choices – Physical Activity
Learning and teaching approach	<ul style="list-style-type: none"> ▪ Interactive non-didactic
Facilitator	<ul style="list-style-type: none"> ▪ Registered healthcare professional with experience working with people with diabetes.
Facilities	<ul style="list-style-type: none"> ▪ Community centres based across the National Health Services in the United Kingdom.
Evaluation	<ul style="list-style-type: none"> ▪ Pre-assessment of HbA1c, blood pressure, fasting lipids, weight, and waist measurement before attending the first education session.
Follow up or support system	<ul style="list-style-type: none"> ▪ Written materials included for future reference. ▪ The written materials enable participants to monitor their type 2 diabetes efficiently, such as to identify when their control is inadequate and know when to seek professional help.
Resource/s	<ul style="list-style-type: none"> ▪ Written materials

A multi-centre randomised controlled trial comparing the effectiveness of the enhanced motivational interviewing intervention with the usual care for reducing cardiovascular risk (MOVE-IT).

MOVE-IT is a randomised controlled trial (RCT) aimed at supporting healthy lifestyle mainly promoting physical activity and healthy eating to reduce the risk of cardiovascular disease, by integrating motivational interviewing and cognitive behavioural therapy (Bayley *et al.*, 2015). Table (4.2) summarises the main characteristics of MOVE-IT.

Studies report that the lack of physical activity and the increasing number of people with obesity in the United Kingdom (Hardoon *et al.*, 2011) contribute to the risk of CVD, which has led to the development of a trial focused on physical activity and diet modification. Moreover, this innovative RCT aimed to assess and to compare a group and individual psychoeducational intervention through the employment of motivational interviewing and cognitive behavioural therapy for people who are at risk of developing CVD. The structured intervention manual is highly relevant for the MY DEUMI intervention manual.

Table 4.2: Characteristics of the multi-centre randomised controlled trial comparing the effectiveness of the enhanced **motivational interviewing** intervention with the usual care for reducing cardiovascular risk (MOVE-IT) study.

Criteria	Characteristic
Target audience	<ul style="list-style-type: none"> Adults aged between 40 and 74 years old at a higher risk of developing cardiovascular disease (CVD), with no known evidence of other chronic diseases.
Structure	<ul style="list-style-type: none"> Consists of three arms, namely; (i) usual care; (ii) individual intervention, and (iii) group intervention. A twelve-month programme with a total of ten sessions divided into two phases (intensive and maintenance). The intensive phase consists of six sessions delivered weekly and four maintenance sessions at three (3), six (6), nine (9) and twelve (12) months, for progress review and problems identification.
Content	<ul style="list-style-type: none"> Three sessions of physical activity Three sessions on healthy eating Four sessions of follow-up and review of the action plan.
Learning and teaching approach	<ul style="list-style-type: none"> Combination of principles and techniques of motivational interviewing, cognitive behavioural therapy and social cognitive theory. Teaching aid utilised to supplement the psychoeducational intervention such as visual aids of food labels, exercise demonstration, video and audio material, meal planning, as well as text and email reminders.
Facilitator	<ul style="list-style-type: none"> Healthy lifestyle facilitator with specific training/competency level to deliver the curriculum.
Facilities	<ul style="list-style-type: none"> The session conducted at local venues, such as community centres and health centres (hospital or GP).
Evaluation	<ul style="list-style-type: none"> The primary outcomes are changes in weight and physical activity (average number of steps per day), while the secondary outcomes are changes in the cholesterol level and CVD risk score, amount of at least moderate physical activity in longer than ten minutes using the accelerometer, dietary recall, health beliefs and depression score.
Follow up or support system	<ul style="list-style-type: none"> Four maintenance sessions to review participants progress and resolve any setback.
Resource/s	<ul style="list-style-type: none"> Written workbook.

4.4.2 Printed and written materials in Malaysia

To further develop the intervention manual and to take into consideration local practices a scoping exercise of available printed and written material was conducted. Once resources were identified review was conducted by the researcher, the supervisor and health professionals from the local institutions in Malaysia providing diabetes care to provide face validity. The panel consisted of, Dr Kirsty Winkley, a diabetes specialist nurse and health psychologist from KCL with research interests in complex interventions using enhanced psychological therapy for people with T2DM to support self-care and improve glucose control. The second panel comprised of 3 health professionals (Ms Jainah Mansor, a diabetes nurse; Ms Maryam Mahmood, a health education officer; and Mrs Fathiah Hani Mohd Ismail, a dietitian) who routinely provide care in primary care clinics in Malaysia.

The review of the available printed material was based on four criteria: (i) content; (ii) written presentation; (iii) research quality; and (iv) visual appeal (Statewide Instructional Resources Development Center, 2006). Table (4.3) is the checklist employed for the reviewing exercise. Figure (20, 21 and 22) display some of the screenshots from the scoping exercises undertaken.

Table 4.3: The rubric score employed in the scoping review of the printed materials.

Criteria	Excellent	Good	Satisfactory
Content	<input type="checkbox"/> Accurately utilises research information in the brochure	<input type="checkbox"/> Employs research information with an adequate degree of accuracy	<input type="checkbox"/> Employs research information with a fair degree of accuracy
Written Presentation	<input type="checkbox"/> Well organised content <input type="checkbox"/> Attractive and well-designed format <input type="checkbox"/> Clear and easily understood message <input type="checkbox"/> Computer generated with strong visual appeal	<input type="checkbox"/> Content is organised <input type="checkbox"/> Format is adequate <input type="checkbox"/> The message is sufficiently understood <input type="checkbox"/> Computer generated with acceptable visual appeal	<input type="checkbox"/> Content lacks organisation <input type="checkbox"/> The format is difficult to follow and poorly organised <input type="checkbox"/> Message not clearly understood <input type="checkbox"/> Computer generated but poorly designed
Research Quality	<input type="checkbox"/> Use of reliable sources <input type="checkbox"/> Accurate analysis of research	<input type="checkbox"/> Sources have some reliability <input type="checkbox"/> Adequate analysis of research	<input type="checkbox"/> Questionable reliability of sources <input type="checkbox"/> Basic information with questionable accuracy
Visual Appeal	<input type="checkbox"/> Imaginative; original <input type="checkbox"/> Use of graphics makes the message "come alive."	<input type="checkbox"/> Creativity is acceptable <input type="checkbox"/> Use of graphics adequate to present message	<input type="checkbox"/> Little creativity used <input type="checkbox"/> Poor selection of graphics

Adapted from (Statewide Instructional Resources Development Center, 2006)

Figure 20: During the scoping study, locally (Malaysia) available printed materials (newspaper adverts) were also considered to be included to complement the resources for the intervention manual.

materials presentation 15032016

Home Insert Design Transitions Animations Slide Show Review View

Scoping Study for Phase 1 MY DEUMI

Written materials Website

2 Poster and Newspaper advert

3

4

Criteria	Excellent	Good	Satisfactory
Content	<input type="checkbox"/> Accurately utilizes researched information in the brochure	<input type="checkbox"/> Employs research information with an adequate degree of accuracy	<input type="checkbox"/> Employs research information with a fair degree of accuracy
Written Presentation	<input type="checkbox"/> Well organized content <input type="checkbox"/> Attractive and well designed format <input type="checkbox"/> Clear and easily understood message <input type="checkbox"/> Computer generated with strong visual appeal	<input type="checkbox"/> Content is organized <input type="checkbox"/> Format is adequate <input type="checkbox"/> Message is sufficiently understood <input type="checkbox"/> Computer generated with acceptable eye appeal	<input type="checkbox"/> Content lacks organization <input type="checkbox"/> Format is difficult to follow and poorly organized <input type="checkbox"/> Message not clearly understood <input type="checkbox"/> Computer generated but poorly designed
Research Quality	<input type="checkbox"/> Use of reliable sources <input type="checkbox"/> Accurate analysis of research	<input type="checkbox"/> Sources have some reliability <input type="checkbox"/> Adequate analysis of research	<input type="checkbox"/> Questionable reliability of sources <input type="checkbox"/> Basic information with questionable accuracy
Visual Appeal	<input type="checkbox"/> Imaginative, original <input type="checkbox"/> Use of graphics make the message "come alive"	<input type="checkbox"/> Creativity is acceptable <input type="checkbox"/> Use of graphics adequate to present message	<input type="checkbox"/> Little creativity used <input type="checkbox"/> Poor selection of graphics

Adapted from Statewide Instructional Resources Development Center 2006

Figure 21: During the scoping study, locally (Malaysia) available printed materials (pamphlets) were also considered to be included to complement the resources for the intervention manual.

materials presentation 15032016

Home Insert Design Transitions Animations Slide Show Review View

Paste New Slide Section Layout Reset

B I U abc X² X₂ AV A₃ A

Convert to SmartArt Picture Text B

16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1 0 1 2 3 4 5 6 7 8 9 10

Pamphlet

12

13

14

Pamphlet

Reduce SUGAR

HEALTHY EATING SERIES

Limit the intake of sugar to 10 teaspoons a day

Beware of hidden sugar in food and drinks

healthy eating

1 Minimise sugar
2 Minimise salt
3 Minimise oil
4 More fruits
5 More vegetables

Sugar level in our (local cuisine)

Type	Weight (g) per piece	Sugar content (g) per piece	1 teaspoon (5 g)
Kuah kari	10-40	16-20	4%
Kuah kari	40-80	16-10	2%
Beri muka	100-120	16-10	2%
Doughnut	40-60	7-10	1%
Kuah tape	120-140	5-7	1%
Lepat pisang	60-70	16-10	2%
Corn Pudding	70-80	10-10	1%
Bingka ubi kayu	70-80	16-20	4%

Sugar level in (drinks)

Drink	Weight (g)	Sugar content (g)	1 teaspoon (5 g)	
Orange	13.20	270	37.8	7.1%
Lime juice	14.15	332	47.6	9.1%
Road beer	11.53	342	38.4	8%
Coke	17.25	295	32.1	6.1%
Mango juice	12.20	250	30.7	6%
Grape juice	12.84	250	32.1	6.1%

Malaysia Diet Guide, 1999

Ministry of Health Malaysia
Health Promotion Board
Kuala Lumpur

Criteria

Excellent

Content

Accurately utilizes researched information in the brochure

Written Presentation

Well organized content
Attractive and well designed format
Clear and easily understood message
Computer generated with strong visual appeal

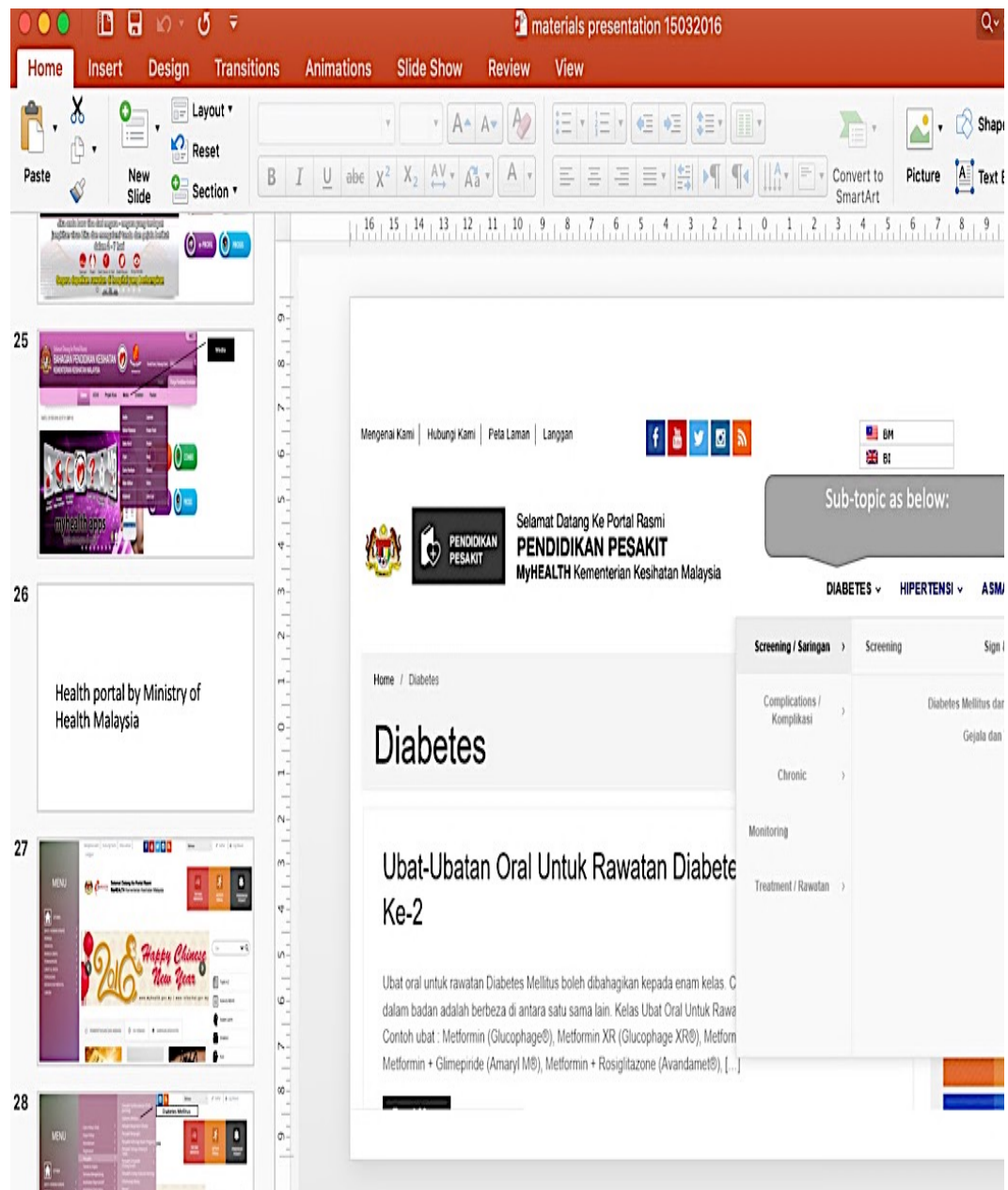
Research Quality

Use of reliable sources
Accurate analysis of research

Visual Appeal

Imaginative; original
Use of graphics make the message "come alive"

Figure 22: During the scoping study, information from the health portal by the Ministry of Health Malaysia was also considered to be included to complement the resources for the intervention manual.



Printed materials such as posters, brochures and newspaper advertisements were used to supplement the manual of the MY DEUMI intervention after a series of discussions with the panels.

The second panel suggested that the list of printed guidelines for T2DM management in Malaysia should be useful. One of the primary references suggested was the 5th edition of Clinical Practice Guideline: Management of Type 2 Diabetes Mellitus issued in December 2015 (see Figure 23) by the Ministry of Health Malaysia (MOH) (Ministry of Health Malaysia, 2015). This evidence-based guideline was developed to guide healthcare professionals in Malaysia. Therefore, most of the content regarding T2DM in the MY DEUMI manual are sourced from this guideline. The second item recommended was the Diabetes Education Manual 2016 (see Figure 24) created by the Malaysian Diabetes Educators Society (Malaysian Diabetes Educators Society, 2016), which is a guide for diabetes educators in Malaysia to ensure the consistency of the information delivered in their education sessions. The Diabetes Education Manual 2016 is particularly useful as it includes an exchange list of carbohydrate and sugar content for local dishes, fruits, vegetable, as well as specific protein and carbohydrate sources, which are of high consumption in Malaysia.

Figure 23: Printed material by the Ministry of Health Malaysia to guide health professionals.

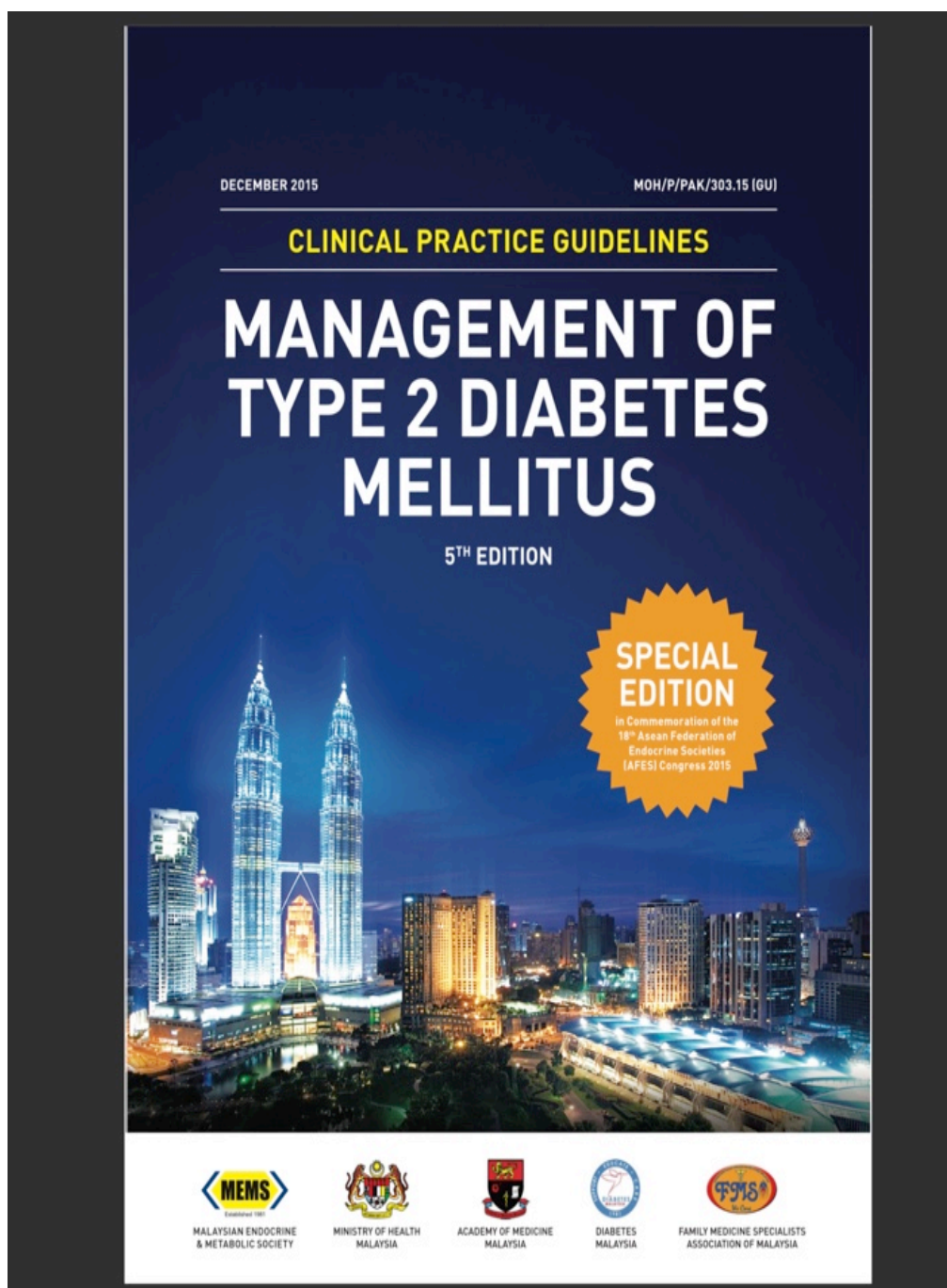
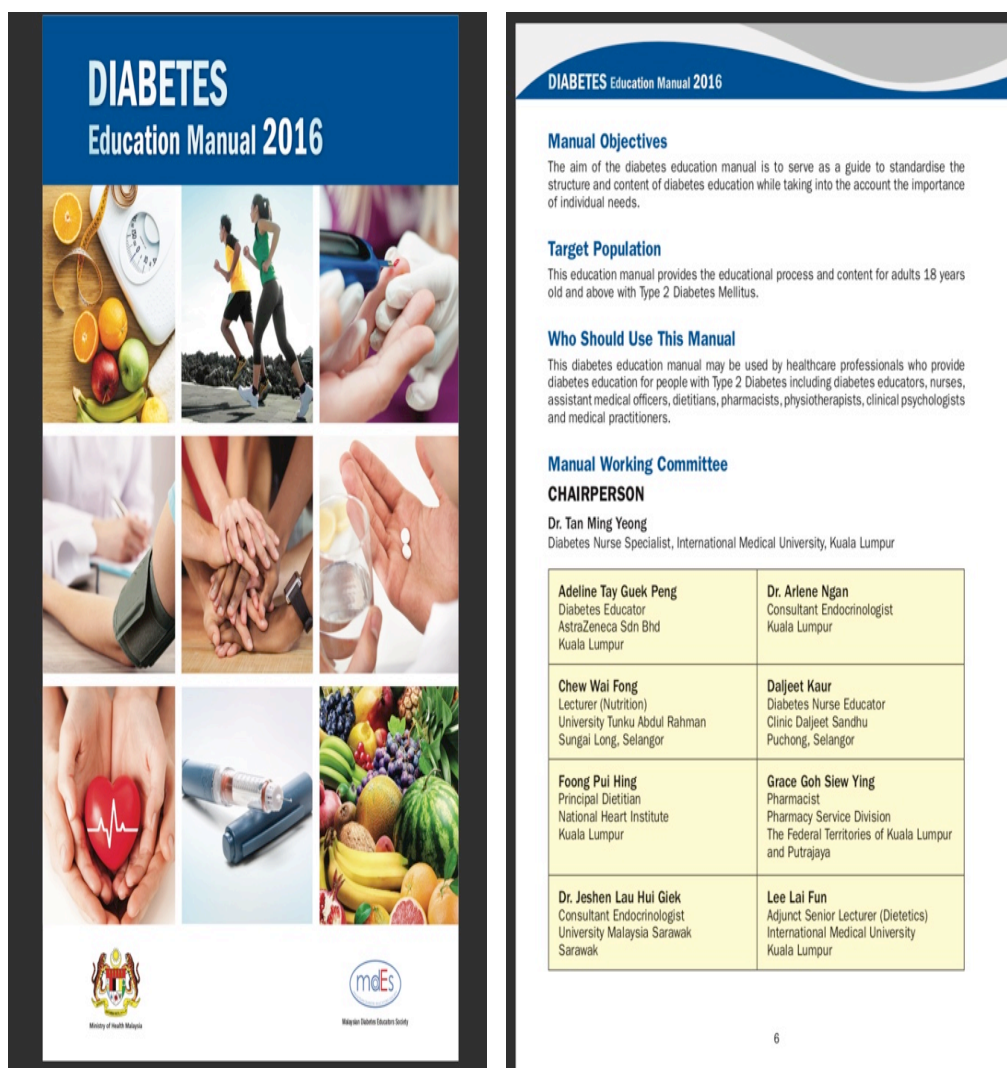


Figure 24: Printed materials by the Malaysian Diabetes Educators Society to guide health professionals.



4.5 Guidelines, theoretical basis and delivery approach of the MY DEUMI intervention

4.5.1 Available guidelines from the United States and Malaysia

4.5.1.1 *Guidelines from the American Association of Diabetes Educators (AADE) and the American Diabetes Association (ADA) task force*

This section gives an overview of the National Standards for DSME by the AADE and ADA which aims to provide diabetes educators with the latest evidence-based research to aid delivery of efficient and supportive diabetes education. As these are not used in Malaysia, the content of the MY DEUMI intervention manual adapts some of the elements in the standards. The standard is a guideline used to assist healthcare providers in the planning and development of effective DSME. The ten standards are updated every five years to ensure the latest evidence for diabetes care is disseminated. The most recent report in 2017 highlights the on-going support and psychological approach for people with diabetes (Beck *et al.*, 2017). Table 4 summarises the ten standards.

The development of the MY DEUMI intervention manual was made within the context of these standards. The main elements adapted and included are: the evaluation of population served; Diabetes Self-Management Education and Support (DSMES) team; curriculum; individualisation; on-going support; and participants progress.

Table 4.4: Summary of the National Standards for DSME developed by the AADE and the ADA task force.

Standard 1 Internal structure	<ul style="list-style-type: none"> Any DSME programme should comprise of formal organisational structure, clear mission statement and provide goals to be achieved.
Standard 2 Stakeholder input	<ul style="list-style-type: none"> It must have explicit lists of the stakeholders (people with diabetes, community interest group etc.) and the experts (Physician, nurse, dietitian, diabetes educator etc.) involved in the programme. Reflection input from the respective stakeholders may be useful for the improvement of the DSME programme.
Standard 3 Evaluation of Population Served	<ul style="list-style-type: none"> Needs assessment is vital for the DSME provider to ensure the delivery method and information given are suitable for the target populations.
Standard 4 Quality Coordinator	<ul style="list-style-type: none"> A coordinator should be available to monitor and ensure the programme runs smoothly and efficiently.
Standard 5 DSMES Team	<ul style="list-style-type: none"> One or more instructors should be involved in the designing, planning and delivering of the DSME programme. At least one of the facilitators facilitating the programme must be a registered nurse, dietitian, nutritionist or pharmacist holding a diabetes educator certificate.
Standard 6 Curriculum	<ul style="list-style-type: none"> A written evidence-based curriculum serves as the framework. The following are the suggested topics to be incorporated: <ul style="list-style-type: none"> * Disease process * Diet management * Physical activity * Safe medication usage * Monitoring glucose level * Preventing complications * Developing strategies to address psychosocial issues and lifestyle * Problem-solving
Standard 7 Individualisation	<ul style="list-style-type: none"> The instructor work with the person with diabetes to develop the action plan for behavioural changes by catering for individual needs.
Standard 8 On-going support	<ul style="list-style-type: none"> The instructor will plan the follow-up activity to provide on-going support and evaluate outcomes.
Standard 9 Participants progress	<ul style="list-style-type: none"> The provider will evaluate the outcome using appropriate measurable tools.
Standard 10 Quality improvement	<ul style="list-style-type: none"> The provider identifies weaknesses and gaps in the programme and how it can be improved from the outcome and vice versa.

4.5.1.2 The Malaysian Clinical Practice Guidelines (CPG): Management of Type 2 Diabetes Mellitus

Type 2 Diabetes Mellitus remains one of the major non-communicable diseases in Malaysia, leading to chronic complications and an increased cost of healthcare. People with T2DM, their carers' and community have the right to be educated and offered a holistic diabetes management of T2DM. Therefore, the CPG (Ministry of Health Malaysia, 2015) aims to equip health professionals with up-to-date literature and evidence, to deliver safe care and reduce variation in practice.

The guideline was developed through a task force consisting of endocrinologists, paediatric endocrinologists, family medicine specialists, public health physicians, general physicians and dietitians. Literature search was carried out to identify studies related to topics in the guideline and are largely from findings of systematic reviews and meta-analyses, graded using the scale from the United States and 'Canadian Preventive Services Task Force and Scottish Intercollegiate Guidelines Network (SIGN).

4.5.1.3 Discussion and conclusion

As mentioned above, findings from the scoping and review of available guidelines across different countries generally discuss and recommend practice, which were synthesised from reliable evidence-based exercises.

The primary aim of the guidelines is to provide recommendations to assist health professionals in all countries, in the prevention, identification, diagnosis and management of people with T2DM. However, the researcher found that DSME guide is not explicitly described in the CPG (the latest is the 5th edition and has been revised every five years), compared with the guidelines by the AADE and ADE, which were

developed specifically for DSME. There were only four pages of recommendation regarding diabetes education, which includes the list of contents of diabetes education and strategies of educations in the form of a flow chart, and the list of team members that should deliver the educational sessions in the primary care clinics in Malaysia.

Despite the lack of input regarding DSME in the Malaysian CPG for T2DM management, in 2016, the Malaysian Diabetes Educators Society developed the first Malaysian Diabetes Education Manual, which explicitly detailed the information needed by diabetes educators in Malaysian healthcare setting, in order to deliver their educational sessions. The guidelines adopt the AADE⁷TM Self-Care Behaviour System (healthy eating, being active, monitoring, taking medication, problem-solving, reducing risks and healthy coping), and the content was written specifically for Malaysians. For example, the list of calories for local savoury dishes and the list of the glycaemic index for Malaysian main carbohydrates.

Finally, due to the unavailability of DSME or SDE, or any specific protocol for developing DSME in the Malaysian healthcare setting, the researcher has decided to synthesise the content from the guidelines by the AADE and the ADA for DSME development. This practice has enabled the researcher to systematically develop the written curriculum for the MY DEUMI intervention. For instance, the adaptation of some of the elements from the National Standards for DSME by the AADE and the ADA Task Force, for the MY DEUMI intervention.

4.5.2 Theoretical framework of the manual of MY DEUMI (written curriculum)

4.5.2.1 An overview of Outcome-based education (manual of MY DEUMI development framework)

This section explores some of the basic principles of outcome-based education (OBE) and how they were used to guide the development of the written curriculum of MY DEUMI. Spady is the expert who articulated and defined this educational concept. Spady defined outcome-based education as ‘the planning and implementing of educational instruction based on the outcome we would like to achieve’ (Spady, 1988, p. 6).

The OBE concept was critiqued by people who claimed that this concept limits learning by focusing only on the outcome and that the standard of the outcome is variable (Rasha and Nisha, 2013). Therefore in 1994, the model was refined with the inclusion of a structured curriculum and an assessment method to evaluate the outcome to enhance learning (Spady, 1994). This concept is geared towards a student-centred approach because it focuses on what the learners can do (specific) at the end of an educational session compared to the general course objectives, which focuses on what the facilitator expects learners to know at the end of the session.

Therefore, the basic principles of OBE were adapted for the MY DEUMI intervention to promote self-directed learning, using active participation to improve cognitive understanding, and by producing clear objectives and evaluation strategies.

The central point of this section is to discuss the reason for embracing the principles of OBE in the manual development, which are as follows:

- i. It will guide the content and activities of the manual based on the intended outcome.
- ii. The focus point will be the learners' (participants') behavioural change, and what should be learned.
- iii. It focuses on how the accomplishment can benefit the learners (participants).

To put these principles into practice, each session of the MY DEUMI intervention manual was developed with one or more specific achievable outcomes to guide the participants toward better self-management. The manual was designed to assist participants to achieve these outcomes using relevant and evidence-based content through a variety of teaching strategies.

4.5.2.2 Behavioural change theory underpinning the intervention manual

The MY DEUMI intervention manual is underpinned by the Theory of Planned Behaviour as it is a useful guide for the initiation of behaviour change, which focuses on the importance of intention towards behavioural change (Friedman, 2011), and the Social Cognitive theory, which emphasises on the importance of significant others in shaping behaviour and supporting the group mode of delivery of the intervention (Bandura, 1986). Applying theory to the development of behavioural and educational interventions is associated with improved knowledge and behaviour change (Fishbein and Yzer, 2003; Whittingham *et al.*, 2008).

Theory of Planned Behaviour by Ajzen (1991)

The Theory of Planned Behaviour (TPB) is an established extension from the Theory of Reasoned Action by Fishbein & Ajzen 1975, which suggests that an intention is the immediate predictor of a given behaviour. However, an intention is not long-lasting and is subject to change over time, and therefore Ajzen proposed that a person's intention is a combination of attitude towards behaviour and other's perception known as subjective norm (Ajzen, 1991).

In addition, another factor was also added, which describes how a person perceives their ability to behave in a certain way, known as perceived behavioural control, and is comparable to the self-efficacy concept by Bandura (Bandura, 1997). Each of the three intention determinants: (i) attitude toward behaviour; (ii) subjective norms; and (iii) perceived behavioural control, drives behavioural intention and subsequent behaviour. Figure (25) illustrates the Theory of Planned Behaviour by Ajzen (1991). Existing reviews regarding the effectiveness of health behaviour theory suggest that TPB can be applied to predict certain behaviours and is widely used in health-related research and can be beneficial when trying to identify factors that may influence behavioural change (Armitage and Conner, 2001; Taylor *et al.*, 2006; Munro *et al.*, 2007).

The Social Cognitive Theory by Bandura (1986)

The social cognitive theory was derived from the Social Learning Theory (SLT) in 1960 by Albert Bandura, which suggested that an individual learn from observing others, and not only through their own experiences. Bandura proposed the Social Cognitive Theory (SCT) as a result of dissatisfaction with the concept of behaviourism, which assumes that all behaviour is dependent on external stimuli.

The SCT propose that learning occurs by an interaction between behaviour, cognitive capability and surrounding environment, and this reciprocal interaction is dynamic. Furthermore, the three core determinants (knowledge, perceived self-efficacy and outcome expectations) are applicable in the context of health care practice and management (Bandura, 2004). This is supported by a review of theories in the health behaviour literature, which aimed to investigate the extent to which theory implementation has occurred in terms of applying, testing or building the theory, and it was concluded that most of the studies included were informed by behavioural change theory (68%, n=198), and the Social Cognitive Theory was one of the most widely used (Painter *et al.*, 2008).

In the context of health, knowledge of health risk, such as the personal cost of the disease, may affect a person's lifestyle, outcome perceptions, and may also shape behaviour. The core element of the SCT is perceived self-efficacy, which explains a person's belief in their ability to execute a required action to gain a positive outcome. To conclude, the mechanism of action explained by this theory, is used in this thesis as a blueprint to formulate how outcomes might be achieved during the MY DEUMI intervention and enabled the matching of activities to the concepts described by the SCT. Figure (26) shows the causal model for the SCT: the interaction between social factors; self-efficacy; outcome expectations; and their influence on behaviour.

Figure 25: The Theory of Planned Behaviour by Ajzen (adapted from Munro et al., 2007).

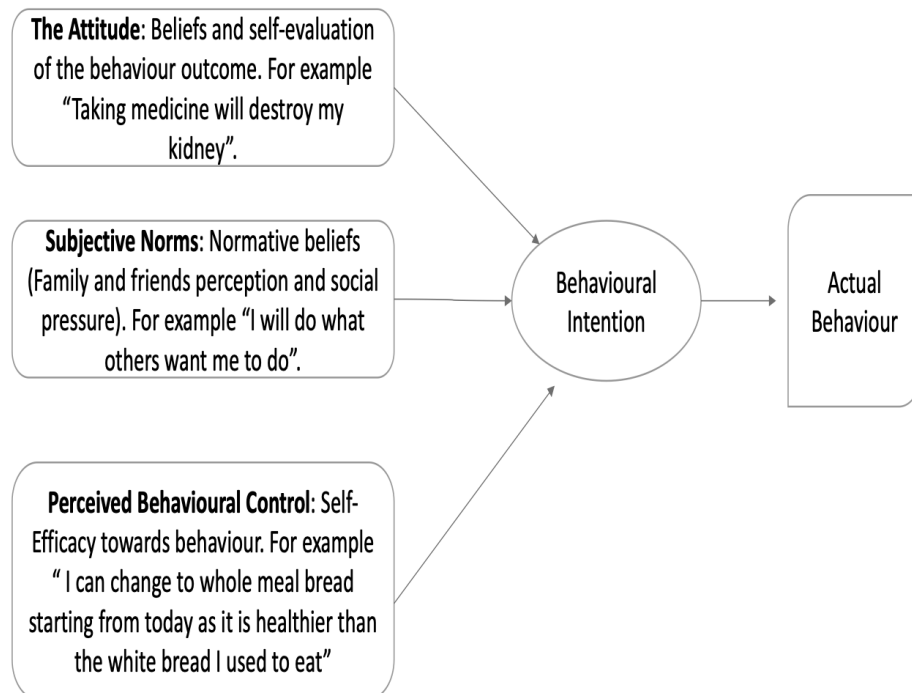
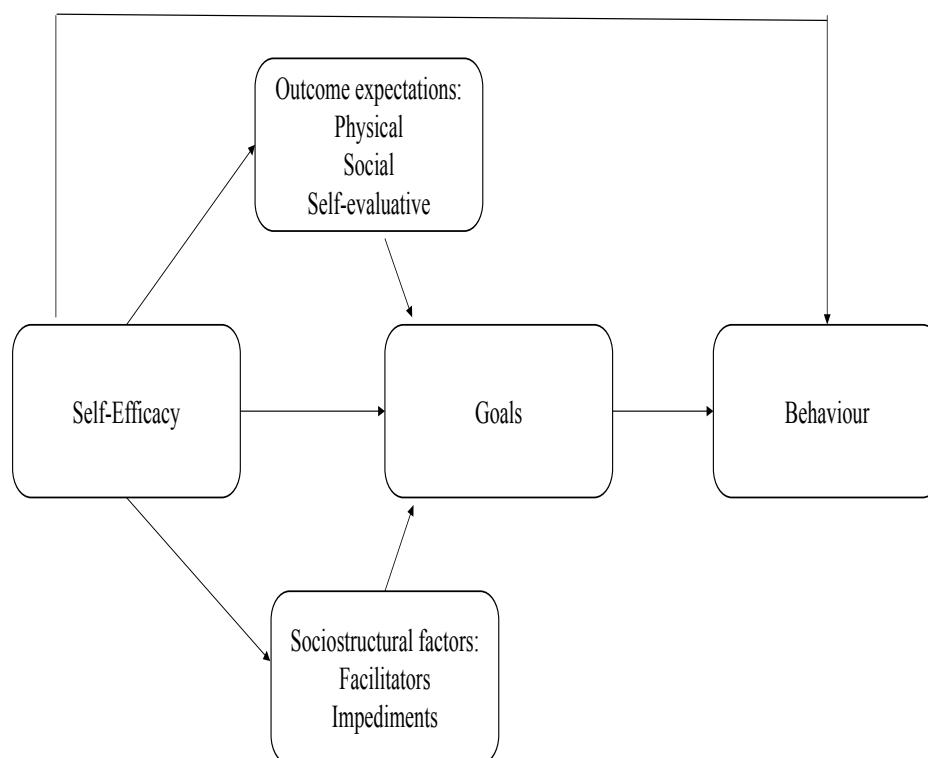


Figure 26: An illustration of the causal model for behaviour in health promotion, in the Social Cognitive Theory adapted from (Bandura, 2004).



4.5.3 Motivational Interviewing as the delivery approach for the MY DEUMI intervention

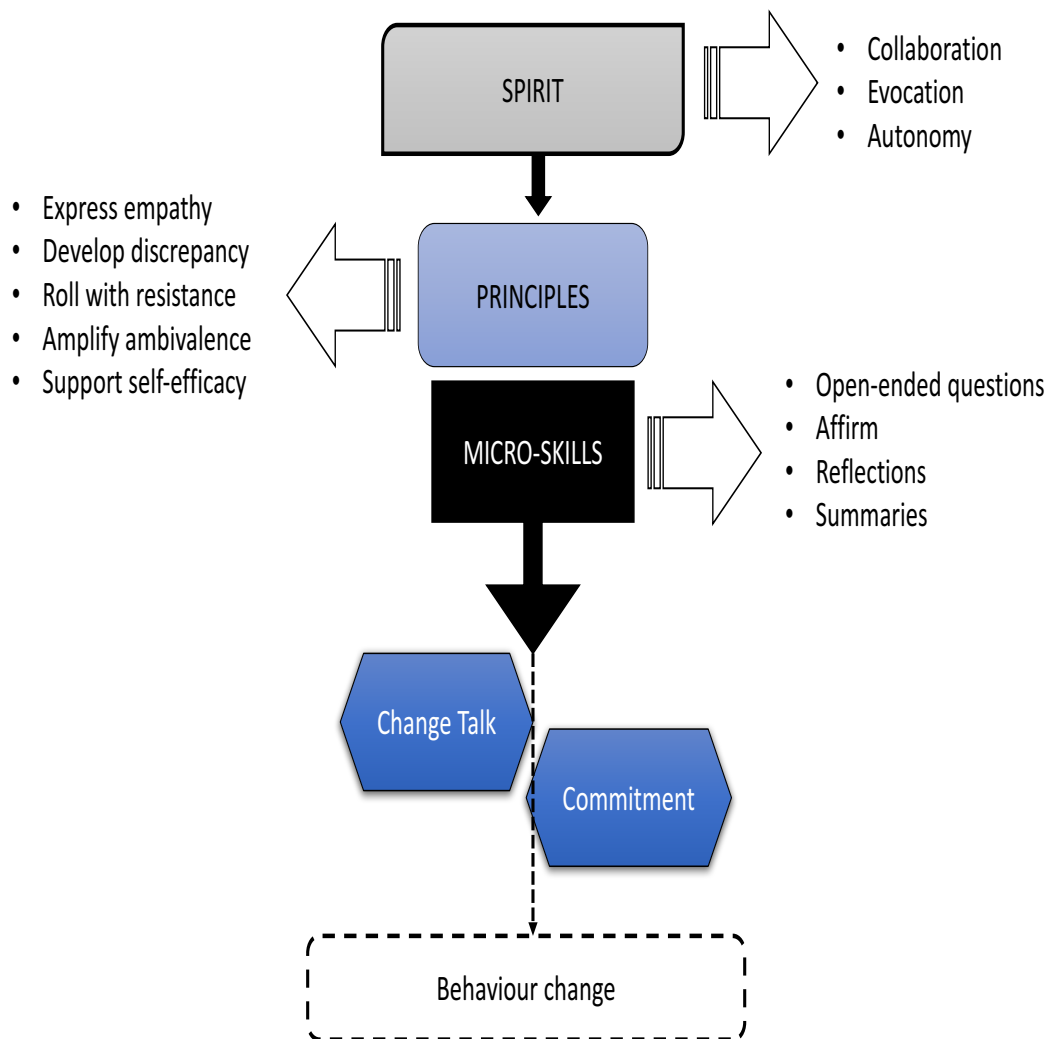
4.5.3.1 *The framework of motivational interviewing*

Motivational interviewing (MI) is technically defined as a client-centred, directive therapeutic style to enhance readiness for change by helping clients explore and resolve ambivalence (Hettema, Steele and Miller, 2005). It is designed to strengthen personal motivation and commitment to a specific goal, by eliciting and exploring the person's reasons for change within an environment of acceptance and compassion (Miller and Rollnick, 2013). Motivational interviewing aims to support the commitment to change and builds on self-efficacy among participants so change can happen through active discussion and effective listening. It nurtures participant's self-evaluation from the facilitator's feedback and reflection to identify the potential for

behavioural change. Figure (27), illustrates the framework of motivational interviewing.

In general, the MI is known as a client-centred approach, meaning that any action should reflect the participant's needs, values and experiences. There are 3 components that make MI more client centred, and is described as the spirit of MI by the founders Miller and Rollnick (Rollnick, Miller and Butler, 2008). The first component is collaboration. In accordance to the MI technique, the facilitator should build the relationship and trust towards mutual understanding. Active discussions from both sides will minimise the dominance of the facilitator who acts as the expert, and resolve the confrontation between them.

Figure 27: The framework of Motivational Interviewing.



The second component is evocation. By implementing MI, the facilitator will try to explore and pick out the participants' own ideas to plan for suitable and achievable actions. Participants are supported to recognise their reason for the change (intrinsic motivation) and are not being told to change. The last element of MI is autonomy. The participants or clients will be given full responsibility for their decision to change, during the active and reflective consultations. However, this can be a challenging task for the facilitators, as the desired outcome may not reflect the person's best interests.

4.5.3.2 Motivational interviewing in practice

Implementation of MI strategies in educational sessions occurs in 2 phases: (i) building motivation to change; and (ii) strengthening commitment to change, as illustrated by (Hall, Gibbie and Lubman, 2012), in an article explaining how health professionals can implement the strategies in their care management, while facilitating them in behavioural changes.

Building motivation to change

Four micro skills of communication are used during the implementation of MI as shown in Figure (28) with the acronym of OARS (O=Open-ended questions; A=Affirmations; R=Reflections; S=Summaries). These basic communication skills are applied to build rapport and create a therapeutic relationship, which aligns with the spirit of MI. The general rule of thumb in MI delivery practice is to ask open-ended questions, followed by 2 to 3 reflections.

Strengthening commitment to change

The next phase is to strengthen the participants' commitment to change which involves goal setting by negotiating a plan of action. The core principles at this stage is for the facilitator to elicit the "change talk", where the participants express their personal views and reasons for change. There are many ways to elicit the "change talk", and the simplest strategy is to seek participants' intention to change by series of questions from four categories as described in Table (4.5), which include examples.

Figure 28: Four micro skills of communication in motivational interviewing.

Ask *open-ended* question



- Create opportunity for the facilitator to understand their values and expectation
- Invite the participants to share their story in their own words
- for example "I understand you have concerns about your sugar level. Can you tell me more about it" versus "Are you concerned about your blood sugar level?"

Make *affirmations*



- Statement of appreciation and understanding
- Supportive measure during the process of change
- Represents their strength to inherent self-worth
- For example "Thank you for your courage to discuss your diet practice. I appreciate this is not easy for you to talk about it."

Use *reflections*



- paraphrasing of participants' statement to show facilitator's understanding
- to amplify desire for change among participants'
- encourage personal exploration by the participants to boost their inner motivation
- Example standard phrases "So you feel...", "It sounds like you..." and "You're wondering if..."

Use *summarising*



- ensure mutual understanding of the discussion
- highlights the discrepancies between the individual's current situation and future desired behaviours
- For example, phrases that begin with "Let me see if I understand so far..." and end with " Anything you would like to add or correct?".

Table 4.5: Eliciting “change talk”.

Change talk	Questions to elicit change talk	Example of “change talk.”
Disadvantages of the status quo	<ul style="list-style-type: none"> • What worries you about your body weight? • What difficulties have resulted from uncontrolled blood glucose level? 	“I guess, if I’m honest and couldn’t control it (diabetes), I may die early and wouldn’t see my children getting married or miss out on my grandkids.”
Advantages of change	<ul style="list-style-type: none"> • What would be different in your life if you lost weight? 	“If I lose weight, at least I won’t have to wake up feeling guilty that I am not taking care of myself.”
Optimism for change	<ul style="list-style-type: none"> • When have you made a significant change in your life before? How did you do it? 	“I did lose some weight a few years ago and I felt so much healthier. It was hard, but it was with the help of my best friend.”
Intention to change	<ul style="list-style-type: none"> • Forget how you would get there for a moment. If you could do anything, what would you change? 	“I want to go back to being healthy and strong, to enjoy my life with friends and family”; “I want to manage my diabetes better.”

Adapted from (Hall, Gibbie and Lubman, 2012).

Generally, the challenges encountered by facilitators in implementing MI is the limited time for consultation. However, this non-judgemental and non-confrontational approach can be simplified and achieved through 5 core principles as described in Table (4.6).

Table 4.6: The five (5) core principles of MI by Miller & Rollnick 1991.

1. Express empathy	<ul style="list-style-type: none"> • Reflective listening is a crucial skill to show the facilitator's understanding of the participants' world, and the reasons for their behaviour. • This mutual understanding creates openness and sharing of their (participants) experiences. • Over time, it helps to reduce the resistance among participants.
2. Develop discrepancy	<ul style="list-style-type: none"> • This element helps participants to understand the importance of behavioural change. Developing discrepancy is affected by a person's values (such as family, quality of life, feelings, etc.) • Once the participants recognise their current behaviour is conflicting with the future goals, this may motivate them towards a lifestyle change.
3. Roll with resistance	<ul style="list-style-type: none"> • Resistance among participants is the consequence of them feeling afraid of change, or they are not ready to change. • Reflections rather than persuasion, can help participants to overcome resistance (explaining the benefits). • Reflections allow more empathy and emphasise autonomy of the individual (participants) to evolve the resistance.
4. Amplify ambivalence	<ul style="list-style-type: none"> • The state of uncertainty to change is acceptable. • Therefore, a direct argument should be avoided to reduce resistance and enhance motivation. • The facilitators have a role in helping participants to resolve ambivalence by identifying the benefits and the consequences to reflect on the dilemma and to look for the best solution themselves.
5. Support self-efficacy	<ul style="list-style-type: none"> • This element is essential for participants who are demotivated, depressed or feeling hopeless. • Self-efficacy is one factor required for a successful change. Therefore, facilitators should focus on how to enhance self-motivation and confidence among the participants, while embracing their autonomy. • Active discussions and having few options might increase their (participants') believe that changes are feasible and viable.

4.5.3.3 Individual vs group motivational interviewing

The detailed justification of the group interventional approach for the MY DEUMI intervention project was discussed as a result following the findings from the systematic review (Chapter 2). This section discusses the differences in the process between individual and group motivational interviewing. Table (4.7) below illustrates the differences between these two approaches in the process of MI delivery (Wagner and Ingersoll, 2013).

Table 4.7: Individual vs Group motivational interviewing.

Process	Individual	Group
Engaging	Helping individuals to share their stories, values and feeling regarding the health problem.	Supporting the group members in building rapport and openness during the discussion, while creating a supportive environment.
Focusing	The setting of topics to discuss.	Exploring perspectives and shaping the focus issues or topics.
Evoking	Elicit change talk to build self-motivation.	Strengthen the members' thoughts, feelings and provide input.
Planning	Exploring options available and explore confidence level.	The discussion is moving towards an action plan. Provide on-going support by encouraging new ideas or options available.

Adapted from (Wagner and Ingersoll, 2013).

Often, MI is implemented face-to-face, but it is possible to adapt it in the form of group therapy (Wagner and Ingersoll, 2013) with good effect. An RCT of intervention for problem gamblers with total participants N= 102 (35 in the individual intervention, 29 in the group-based intervention, 14 waitlist control group for group-based intervention and 14 waitlist control for individual intervention) aimed to seek the effectiveness of the intervention by combining group MI and CBT treatment. It demonstrated significant improvements in terms of frequency of gambling urges and life satisfaction, with the outcomes maintained at 6 months post-intervention (Oei, Raylu and Casey, 2010). Furthermore, a quasi-experimental study investigating the effect of group MI with a total of 155 participants (78 participants receiving the usual treatment as the control group and 77 participants in the group MI intervention), in weight management intervention conducted in the UK, exhibited a significant improvement in the BMI among the intervention group as compared to the control group (existing weight management programme) (Simper, Breckon and Kilner, 2016). Therefore, although not definitive in terms of efficacy and application to the problem of Type 2 diabetes, group MI could be beneficial.

Additionally, group motivational interviewing may offer a different impact compared to individual MI, as it involves interactions between group members, which may enhance the processing of information. The implementation of group MI may be less complicated for the facilitator and less work for the individuals within the group as most of the active discussion is through brainstorming sessions and sharing experiences. The group environment provides an opportunity for change to be contagious among members of the group, while exploring options and planning actions. It may also create positivity and may provide on-going support for members to subtly achieve their personal goals, as suggested in a literature review of small group performance and decision making (Kerr and Tindale, 2004).

4.6 Summary

This chapter presents the intervention development process, which involved integrating the results from the systematic review in Chapter 2, the qualitative study in Chapter 3, and the scoping study as discussed earlier in this chapter. This chapter also elaborates on the theoretical basis, delivery approach and principles for the development of the intervention manual (written curriculum).

Following this, the intervention was adapted into a structured diabetes education programme for Malaysians newly diagnosed with T2DM, and the MY DEUMI intervention manual (structure and content) will be discussed in the next chapter.

Chapter 5 : *Malaysian Diabetes Education Intervention using Motivational Interviewing (MYDEUMI)* format, structure and content for people newly diagnosed with type 2 diabetes mellitus –manual intervention and written curriculum development.

5.1 Chapter scope

This chapter discusses the process of adapting the motivational interviewing (MI) technique to deliver the MY DEUMI intervention. Specifically, this chapter outlines the format, structure and content of the intervention, which consists of eight brief sections.

The first section explains the process of designing a written curriculum grounded by the outcome-based education (OBE) concept. The second section discusses the learning outcomes of the MY DEUMI intervention. Next, the third section explains how the contents were selected. The fourth section outlines the intended outcome of each MY DEUMI intervention session. The next section discusses the methods to accomplish the intervention and also the evaluation strategy for the intended outcomes. Then, the seventh section outlines the final intervention content. The last section briefly highlights the face validity exercise conducted once the intervention manual was fully completed.

5.2 Introduction

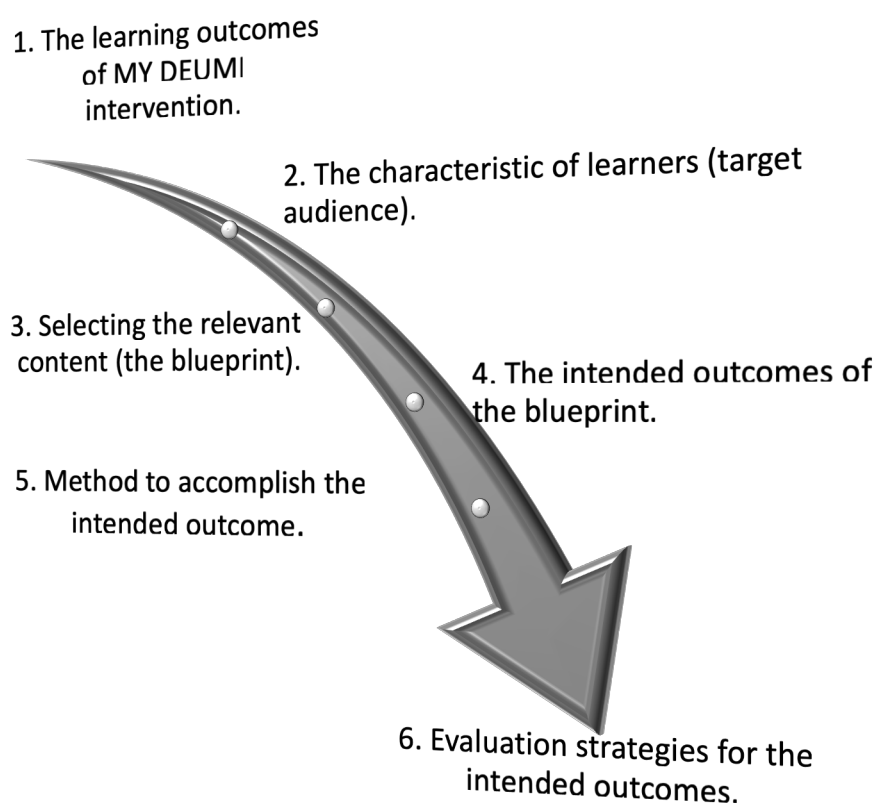
A manualised intervention or written curriculum is recommended to ensure fidelity during the delivery of educational interventions (Horner, Rew and Torres, 2006), as infidelity may occur if the intervention is not delivered the way it was planned and designed. Therefore, in complex intervention studies, an intervention manual or a written curriculum can reduce the risk of variation or deviation during delivery and ensures the reliability of the study findings.

The essential component of a written curriculum according to the OBE concept is to organise the programme to enable learners to successfully achieve the desired outcomes at the end of their learning experiences. According to Spady, as discussed in the previous chapter (Chapter 4), a manual or a written curriculum begins with the formulation of clear objectives, followed by the organisation of the written curriculum and evaluation strategies to ensure learning happens. Therefore, the following sub-topics elaborate the intervention manual (written curriculum) development.

5.3 Process of designing a written curriculum grounded by the outcome-based education (OBE) concept

It is recommended that the learning outcome is pre-determined in order to prepare the learners in any educational programme or course. In the context of this thesis, the ‘learners’ refers to the participants, where the aim is to provide them with the necessary skills and abilities to assist them towards an effective diabetes self-management. Figure (29) illustrates the step-by-step process followed by the researcher to develop the manual of the MY DEUMI intervention.

Figure 29: The process of designing a written curriculum grounded by the OBE concept.



5.4 The learning outcome of the MY DEUMI intervention

Outcomes or objectives of an educational programme describe the purpose and expected results of the educational activities and act as the foundation for evaluation. Learning outcomes are statements formulated to elaborate the learning that the participants have achieved or demonstrated (able to do) at the end of the programme.

The learning outcomes of the MY DEUMI intervention were formulated so that at the end of the intervention the participants are able to achieve the glycaemic control target. The learning outcome for the MY DEUMI intervention is as illustrated in Figure (30).

Figure 30: The learning outcomes of the MY DEUMI intervention.

MY DEUMI participants will demonstrate knowledge of diabetes and gain competency in basic skills of diabetes self-management, such as diet modifications, increased physical activity and adherence to medication as evidenced by glycaemic control.

Apart from that, participants completing the MY DEUMI intervention will gain self-efficacy and the ability to demonstrate competence in diabetes self-management.

5.5 The characteristics of the learners (target audience)

This section discusses the characteristics of the participants involved in the MY DEUMI intervention so that a suitable approach can be specified to promote learning at an optimal level. The inclusion criteria set for this research project is Malaysian adults who are newly diagnosed with T2DM, without complications such as kidney failure, heart disease or retinopathy. The main reason of specifying the inclusion criteria is to ensure the participants were of a homogenous group for a practical and focused discussion during the delivery of the intervention. As this was a group exercise, the concept of adult learning by Knowles (1984) was adopted. Knowles was the first to develop the idea of informal adult education, and proposed a comprehensive theory known as andragogy. The five main assumptions for adult learners by (Knowles, 1984), are explained in Figure (31).

Following the concept of andragogy, the principles were included in the manual to provide effective sessions for the participants. The first element is to set specific objectives or intended outcome for each session, while the second element is to create a manual with flexibility, for example, the information given must be suitable for a broad range of backgrounds, such as for working and non-working participants. The third element inculcated in the manual is the exploration of participants' experiences, as this is also inherent in the DESMOND programme. The sharing of experiences may be of relevance to them, and may be applied in daily diabetes self-management. Additionally, motivational interviewing techniques promote discussion of participants' intrinsic motivations, and allows them to decide on the best option in optimising their diabetes self-management. The final element is to ensure the main sources and references are from local materials to increase their relevance to the participants.

Figure 31: Five main assumptions of adult learners' theory (Andragogy).

Autonomous and self-directed	<ul style="list-style-type: none"> •An adult will learn from active participation with the facilitator. The educator takes the role of a facilitator.
Life experience as foundation	<ul style="list-style-type: none"> •To create a more efficient teaching among adults is to connect through their experience by active discussions or sharing moments.
Goal oriented	<ul style="list-style-type: none"> •An adult's readiness to learn is more likely to occur when there are clear objectives specified for each course.
Practical and relevancy	<ul style="list-style-type: none"> •Normal maturity process in adulthood shapes personal views, for education sessions to be effective, they must be applicable and practical for daily living activities.
Motivation to learn	<ul style="list-style-type: none"> •The most important factor to enable learning to occur is the intrinsic motivation, especially when it involves behavioural modifications.

5.6 Selecting the relevant content (the blueprint of the written curriculum)

This section explains the way the relevant content has been selected for the manual. According to NICE 2015 in the recent Clinical Guideline Update Type 2 diabetes in Adults: Management (NICE Internal Clinical Guidelines Team, 2015), the critical priorities for the implementation of patient education should include a comprehensive dietary management (weight management and diabetes diet modifications), blood pressure control advice, self-monitoring of blood glucose level and drug treatment.

Whereas in the US, the American Diabetes Association focuses on patient centred care through the Chronic Care Model, and one of the core elements is self-management support (American Diabetes Association (ADA), 2016). Elements listed in Figure (32) must be included in order to support self-care practice and successful behavioural changes.

Figure 32: Elements to support diabetes self-management by the American Diabetes Association (ADA).

Healthy lifestyle options such as healthy diet and tobacco use, weight management, physical activity and stress management.

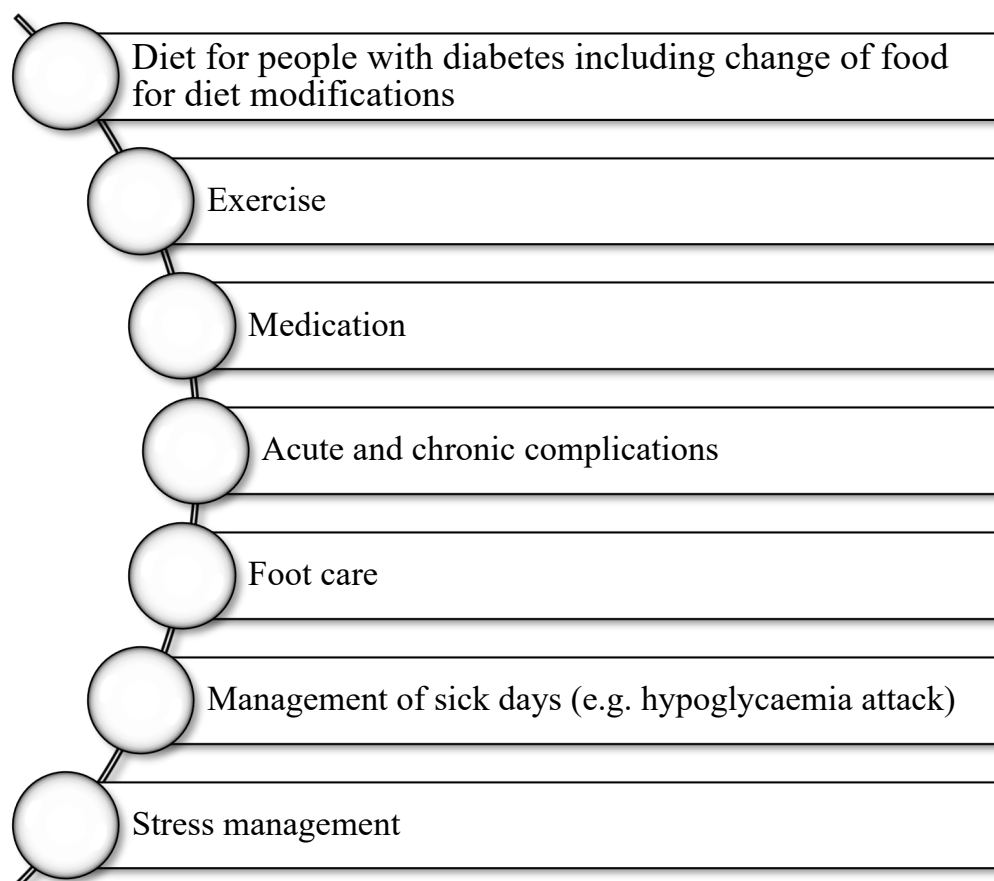
Diabetes management (medication intake, glucose and blood pressure monitoring).

Self-care to reduce complications such as foot care and gradual complications screening.

Problem solving management (goal setting).

The guideline produced by the Ministry of Health Malaysia outlining the scope of education for people with diabetes as listed in Figure (33) is also included.

Figure 33: Scope of education for people with diabetes as recommended by the Ministry of Health Malaysia.



Therefore, the MY DEUMI manual incorporated the topic areas identified in the local and international guidelines, as these would be needed to support behaviour modification for optimisation of diabetes self-management. The topics were finalised after a number of discussions and following the input from the PhD supervisory team to match with total delivery hours, as discussed previously. Table (5.1) explicitly lists the topics that were considered relevant to participants, and these were set as the blueprint of the MY DEUMI intervention manual.

Table 5.1: List of topics included in the MY DEUMI intervention manual.

MY DEUMI topic	The element of diabetes self-management
Introduction 1: Are you ready?	
Introduction 2: Towards effective self-management.	
Session 1: What is diabetes?	General information regarding T2DM
Session 2: Eating in balance: A sweet walk through time.	Diet for people with diabetes
Session 3: Diabetes Medicine	Pharmacological management
Session 4: Keep calm and Let's play <u>as below</u> :	Diet for people with diabetes
1. Food labels.	
2. Sugar game.	
3. Fat game.	
Session 5: Keep moving, stay healthy and lose weight.	Physical activity
Session 6: Move it! Let's play.	Physical activity
Session 7: Diabetes foot.	Foot care
Session 8: Living and coping with diabetes.	Stress management
Session 9: Complementary and alternative medicine.	Complementary and alternative medicine
Session 10: Relapse prevention	Goal setting/ Stress management/Problem solving
Session 11: Yes, I can do it!	Goal setting/ Problem solving

5.7 The intended outcome of the MY DEUMI blueprint

The next process in the manual development was the formulation of the specific intended (immediate) outcomes for each session. This is an important element in designing an educational programme for quality assurance and focusing the direction of learning. This section explains the outcome measured.

An intended outcome consists of a phrase with an active verb while the object indicates participants' action with measurable elements (Winwood and Purvis, 2008). Often, intended outcomes include knowledge, attitudes and skills, as the result of

learning, which is derived from Bloom's three domains of learning¹ (Kennedy, Hyland and Ryan, 2008). Therefore, the researcher has included at least two out of the three components (knowledge, attitude and skill) for each session. The statement of the intended outcome is to guide the facilitator to form participants' expectations and encourage participation. Table (5.2) illustrates the details of the intended outcomes for each of the MY DEUMI intervention session.

Table 5.2: The list of intended outcomes of each session for MY DEUMI intervention.

MY DEUMI topic	Intended outcomes (At the end of the session, participants able to:	Bloom's domain of learning		
		Knowledge	Skill	Attitude
Introduction 1: Are you ready?	<ul style="list-style-type: none"> • Understand the outline of the programme. 			/
Introduction 2: Towards an effective self-management.	<ul style="list-style-type: none"> • Increase optimism and confidence about joining this programme. • Elicit understanding of T2DM and its risk factors. 	/		/
Session 1: What is diabetes?	<ul style="list-style-type: none"> • Elicit understanding of the causes, symptoms and complications of T2DM. • Increase the awareness towards effective self-management. • To formulate individual goal; how and why? 	/	/	

¹ Bloom's three domains of learning suggested that learning is a combination of three (3) domains namely; (1) The cognitive meaning transferring of knowledge; (2) The affective meaning developing an attitude; and (3) The psychomotor meaning generating skills. This model provide a basic framework in any learning instruction development to determine the impact of the implementation.

Session 2: Eating in balance: A sweet walk through time.	<ul style="list-style-type: none"> • Discuss the primary goal of diabetes self-management (blood glucose level). • Elicit knowledge of diet for people with diabetes. • Increase the knowledge of healthy eating through an understanding of low glycaemic index diet and the healthy plate model. • Increase self-efficacy by identification of barriers in meal planning and ways to overcome them. 	/	/	/
Session 3: Diabetes Medicine	<ul style="list-style-type: none"> • Introduce the different types of medications available to treat diabetes. • Understand the mechanism and how these medicines affect our bodies and the possible side effects. • Increase the confidence in consuming diabetes medicine. 	/		/
Session 4: Keep calm and Let's play. <ol style="list-style-type: none"> 1. Food labels. 2. Sugar game. 3. Fat game. 	<ul style="list-style-type: none"> • Elicit the knowledge of the required amount of fat, carbohydrate, sugar and salt per day. • Increase the confidence in reading food labels. • Increase the knowledge of fat content in several types of foods. 	/	/	
Session 5: Keep moving, stay healthy and lose weight.	<ul style="list-style-type: none"> • Elicit the knowledge about physical activity. • Provide information regarding walking and sedentary lifestyle. • Determine the activities that are good for diabetes management. • Determine the amount of activity they should do. 	/		/

Session 6: Move it! Let's play.	<ul style="list-style-type: none"> • Develop the skills that help to increase physical activity. • Increase the confidence to increase physical activity. 		/	/
Session 7: Diabetes foot.	<ul style="list-style-type: none"> • Discuss the risk and complications of diabetic neuropathy. • Conduct foot ulcer risk assessment. • Provide basic information and guidelines for the prevention of foot ulcers. • Increase the awareness regarding the importance of foot care for people with diabetes. 	/	/	/
Session 8: Living and coping with diabetes.	<ul style="list-style-type: none"> • Express their feelings about having diabetes. • Understand the physical response to stress. • Provide ways to cope with emotional impact and to uphold a good quality of life. 	/	/	/
Session 9: Complementary and alternative medicine.	<ul style="list-style-type: none"> • Understand the term of complementary medicine or alternative medicine, and the available treatment. • Elicit the importance of herbal medicine in self-management. • Increase the awareness of the effects of the abuse of herbal medicine to people with diabetes. 	/		/

Session 10: Relapse prevention	<ul style="list-style-type: none"> • Develop self-efficacy and increase their self-confidence for lifestyle modification • Recognise what turns a lapse into a relapse • Reflect on individual hotspots and ways to handle it 	/	/	/
Session 11: Yes, I can do it!	<ul style="list-style-type: none"> • Reflect on what has been gained throughout the programme. • Formulate individual goal/s. 			/

5.8 Methods to accomplish the intended outcome

In order to deliver the topics listed in the previous section and enhance the attractiveness and interactivity of this intervention, hands-on and group activities were included, with the motivational interviewing as the main delivery approach. This is in line with the adult learning and participant-centred approach.

This section specifically explains the methods used to deliver the intervention content and accomplish the intended outcome. The three main methods include:

- i. Motivational interviewing as the delivery approach.
- ii. Hands-on activities to improve diabetes self-management skills, such as reading food labels.
- iii. Interactive activities (group activities and quizzes).

5.8.1 Motivational Interviewing technique

There are four processes involved in the implementation of group motivational interviewing: (i) Engaging; (ii) Focusing; (iii) Evoking; and (iv) Planning, as detailed in Chapter 4 and summarized in Figure (34).

Figure 34: Summary of group motivational interviewing techniques.

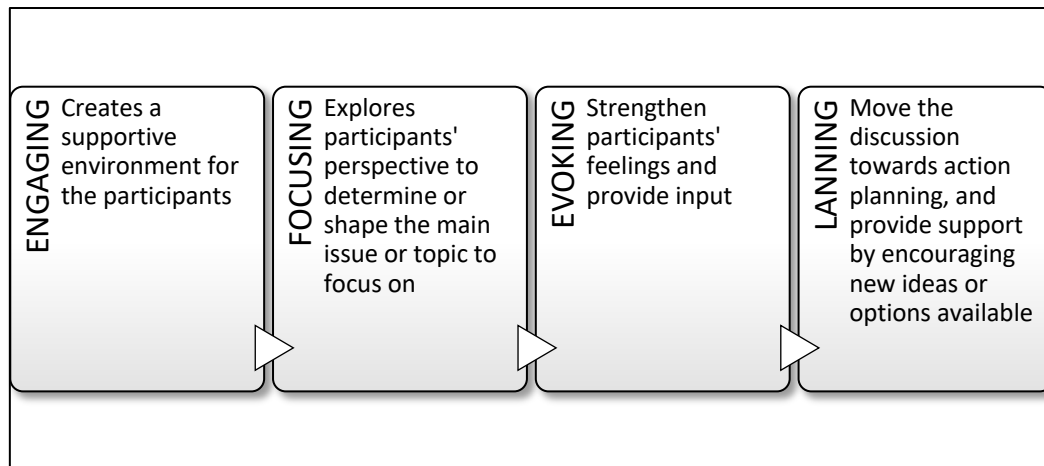


Figure (35, 36, and 37) provide snapshots of the intervention as examples of how each MI component was brought into the delivery of the intervention. Figure (38) and (39) illustrate how the researcher kept the participants engaged during the educational sessions by eliciting members' agreement before the session or reflecting on the previous session before continuing onto the next session.

Figure 35: An Engaging process in the motivational interviewing.

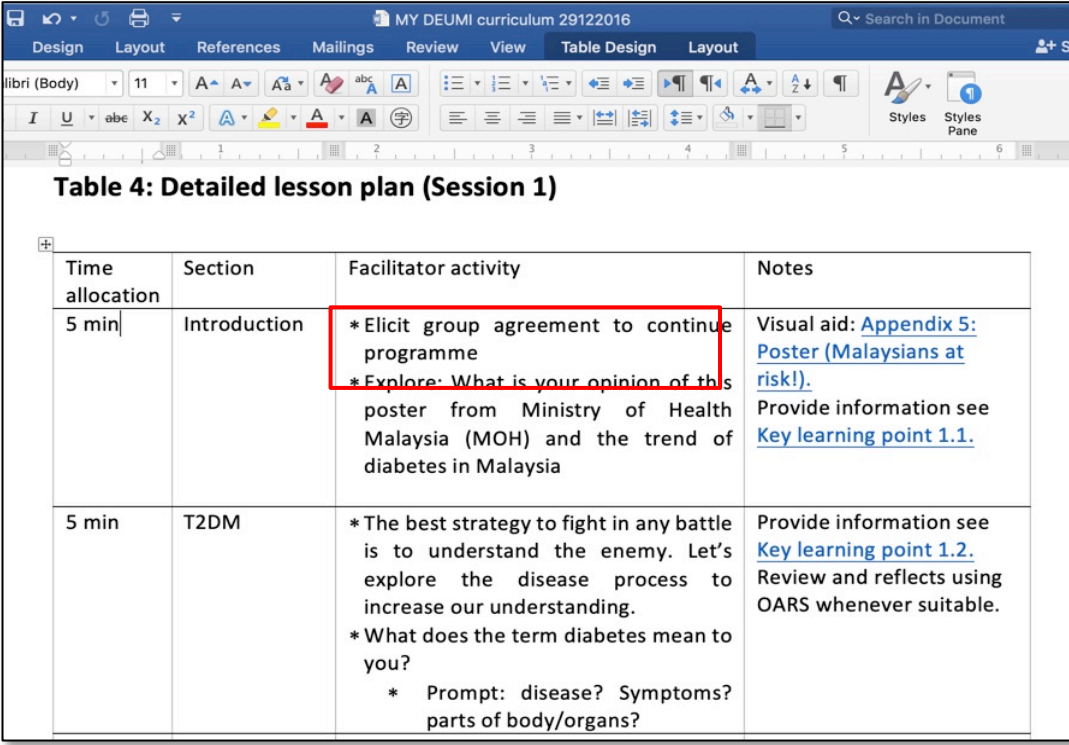


Table 4: Detailed lesson plan (Session 1)

Time allocation	Section	Facilitator activity	Notes
5 min	Introduction	<ul style="list-style-type: none"> * Elicit group agreement to continue programme * Explore: What is your opinion of this poster from Ministry of Health Malaysia (MOH) and the trend of diabetes in Malaysia 	Visual aid: Appendix 5: Poster (Malaysians at risk!) . Provide information see Key learning point 1.1 .
5 min	T2DM	<ul style="list-style-type: none"> * The best strategy to fight in any battle is to understand the enemy. Let's explore the disease process to increase our understanding. * What does the term diabetes mean to you? <ul style="list-style-type: none"> * Prompt: disease? Symptoms? parts of body/organs? 	Provide information see Key learning point 1.2 . Review and reflects using OARS whenever suitable.

Figure 36: An Engaging process in the motivational interviewing.

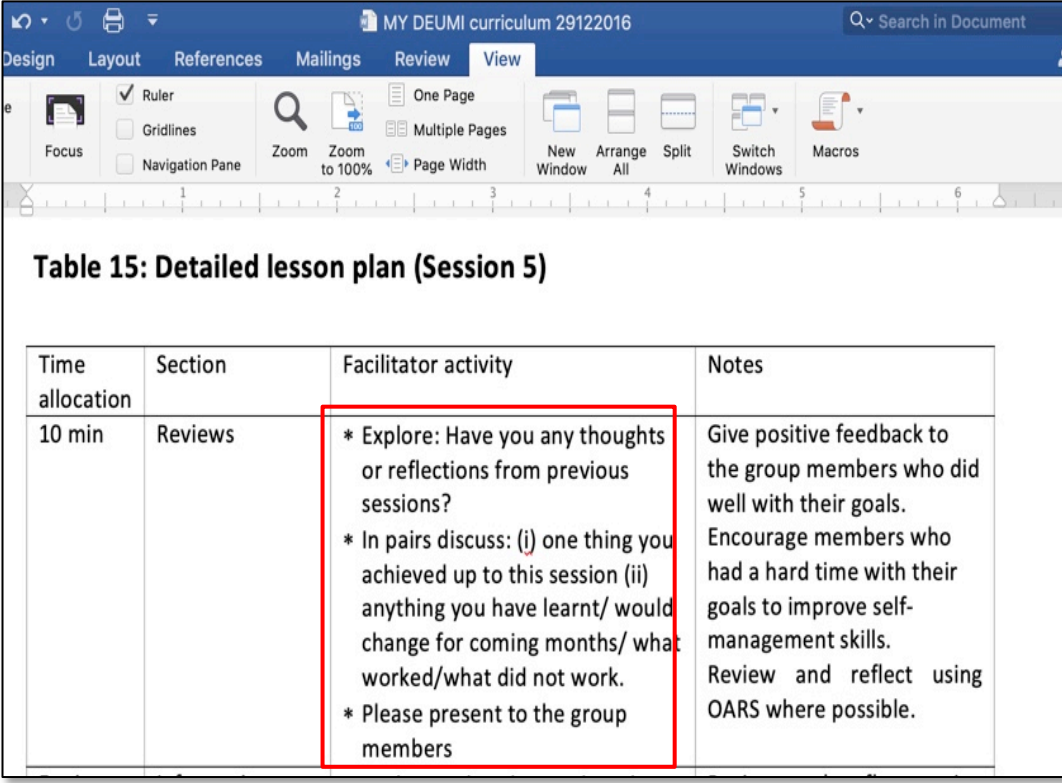
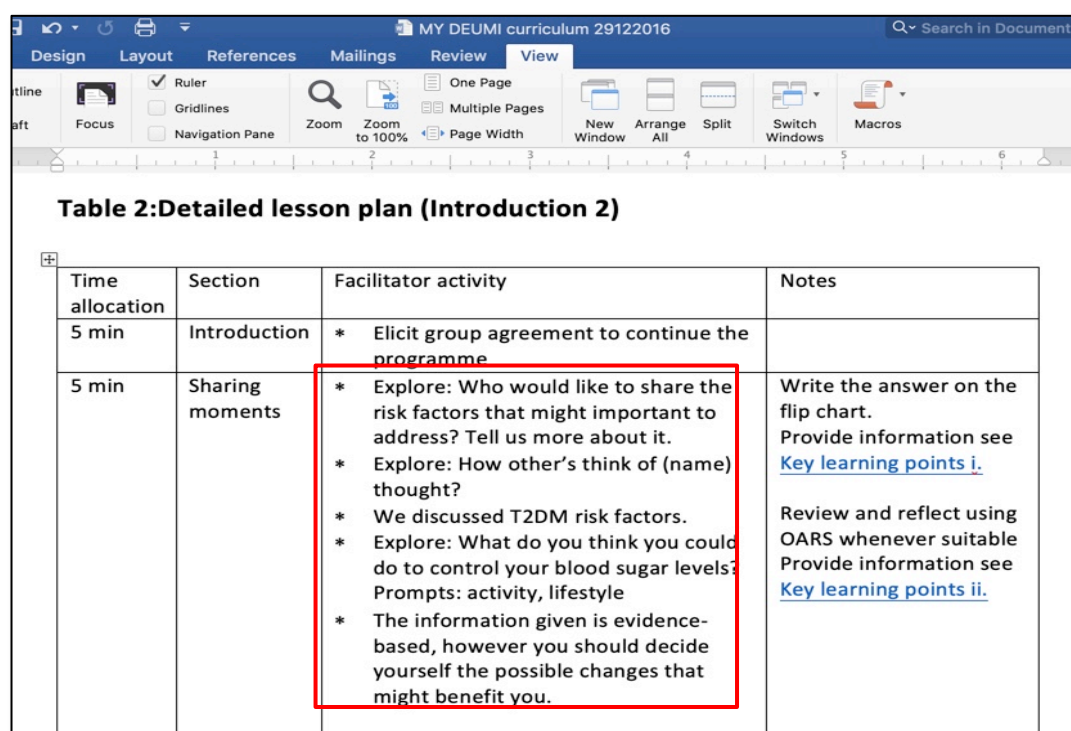


Table 15: Detailed lesson plan (Session 5)

Time allocation	Section	Facilitator activity	Notes
10 min	Reviews	<ul style="list-style-type: none"> * Explore: Have you any thoughts or reflections from previous sessions? * In pairs discuss: (i) one thing you achieved up to this session (ii) anything you have learnt/ would change for coming months/ what worked/what did not work. * Please present to the group members 	Give positive feedback to the group members who did well with their goals. Encourage members who had a hard time with their goals to improve self-management skills. Review and reflect using OARS where possible.

Figure (5.9) is an example of the focusing process in the MI through the exploration of participants' perspectives, or their opinions on what is important and significant for them, prior to the discussion of the main issue or topic.

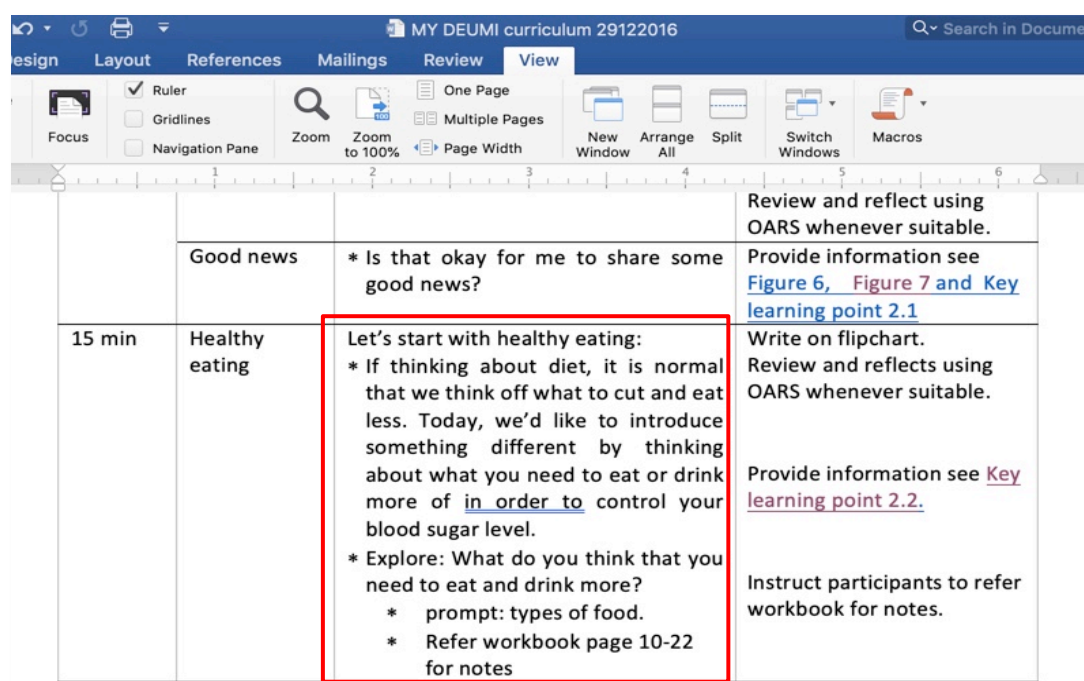
Figure 37: The focusing process in the motivational interviewing.



Time allocation	Section	Facilitator activity	Notes
5 min	Introduction	* Elicit group agreement to continue the programme	
5 min	Sharing moments	<ul style="list-style-type: none"> * Explore: Who would like to share the risk factors that might important to address? Tell us more about it. * Explore: How other's think of (name) thought? * We discussed T2DM risk factors. * Explore: What do you think you could do to control your blood sugar levels? Prompts: activity, lifestyle * The information given is evidence-based, however you should decide yourself the possible changes that might benefit you. 	<p>Write the answer on the flip chart. Provide information see Key learning points i.</p> <p>Review and reflect using OARS whenever suitable Provide information see Key learning points ii.</p>

Moreover, evoking is a crucial process in MI delivery, where the facilitator attempts to explore and elicit participants' motivation to change. During this process, the facilitator looks for "change talk" from the participants. Figure (5.10) is an example of the evoking process in MY DEUMI, through the use of hypothetical questions to explore available options for behaviour change.

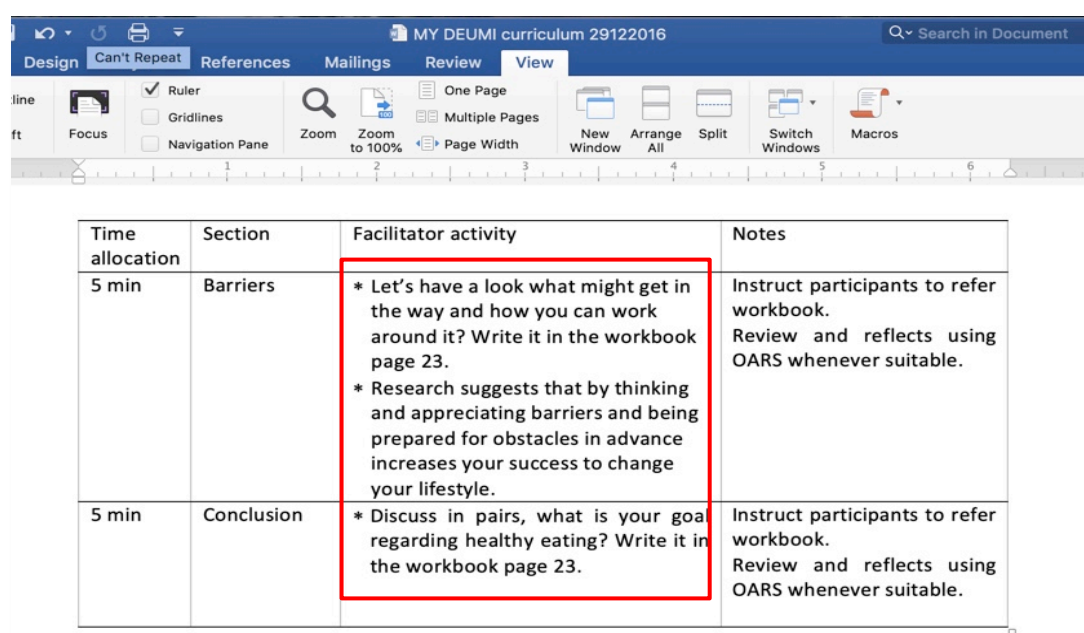
Figure 38: The evoking process in the motivational interviewing.



	Good news	* Is that okay for me to share some good news?	Review and reflect using OARS whenever suitable. Provide information see Figure 6 , Figure 7 and Key learning point 2.1
15 min	Healthy eating	<p>Let's start with healthy eating:</p> <ul style="list-style-type: none"> * If thinking about diet, it is normal that we think off what to cut and eat less. Today, we'd like to introduce something different by thinking about what you need to eat or drink more of <u>in order to</u> control your blood sugar level. * Explore: What do you think that you need to eat and drink more? <ul style="list-style-type: none"> * prompt: types of food. * Refer workbook page 10-22 for notes 	<p>Write on flipchart. Review and reflects using OARS whenever suitable.</p> <p>Provide information see Key learning point 2.2.</p> <p>Instruct participants to refer workbook for notes.</p>

Finally, the discussion mainly focuses on empowering the participants, giving them the autonomy and exploring their ideas on ways they can make changes. Figure (5.11) provides examples of how the facilitator can discuss about setting individual goals with the group members.

Figure 39: The planning process in the motivational interviewing.



Time allocation	Section	Facilitator activity	Notes
5 min	Barriers	<ul style="list-style-type: none"> * Let's have a look what might get in the way and how you can work around it? Write it in the workbook page 23. * Research suggests that by thinking and appreciating barriers and being prepared for obstacles in advance increases your success to change your lifestyle. 	Instruct participants to refer workbook. Review and reflects using OARS whenever suitable.
5 min	Conclusion	* Discuss in pairs, what is your goal regarding healthy eating? Write it in the workbook page 23.	Instruct participants to refer workbook. Review and reflects using OARS whenever suitable.

MY DEUMI facilitator training

The researcher was trained in motivational interviewing to become a Healthy Lifestyle Facilitator (HLF) by a clinical psychologist in the MOVE IT study, a randomised control trial comparing the effectiveness of enhanced MI with the usual care to reduce cardiovascular risk. The training on the technique was held from March 2015 to early May 2015, while the hands-on sessions with 6 other MOVE IT participants have taken place from the end of May 2015 to August 2015. The teaching methods used by the clinical psychologist were mostly practical, such as role-plays, screening of training videos, working on case scenarios, and supervision of training cases. An individual assessment was conducted by the clinical psychologist using a checklist for MI adherence, to evaluate the researcher's competence level as well as for regular supervision during the hands-on session with the MOVE-IT team. The researcher achieved a 93% score for MI adherence during the individual assessment, in which she was assessed on delivering the intervention using the MI technique. The researcher has also previously received post-graduate training in curriculum development, during her MSc in Health Science (Health Education) course at the National University of Malaysia, and holds a certificate of teaching methodology (Professional Certificate in Education and Teaching for Nursing Professionals), obtained through a six-month course at '*Kumpulan Perubatan Johor*' (A Member of Johor Corporation Group) (KPJ) Healthcare University College (KPJUC) Nilai Campus, Malaysia.

5.8.2 Hands-on activities

The hands-on sessions were carried out to achieve the intended outcome, while triggering interest and increasing participations. By definition, hands-on is a knowledge or skill that an individual acquires from doing something rather than just reading about it or seeing it being done (*Cambridge Dictionary*, 2017). This element was included in the MY DEUMI intervention following the systematic review findings, as reported in Chapter 2. Apart from that, the hands-on activities were intended to ensure the participants stay engaged throughout the sessions, and also to provide them with new skills to support their diabetes self-management.

Additionally, this method was supported by a qualitative study looking at the effects of community-based occupational therapy, in their study promoting the learning of handicrafts for elderly African Americans in the remote country-side of North Carolina, indicating that the hands-on experience that they received has helped them to overcome fear and develop self-confidence (Velde, Wittman and Mott, 2007). This notion was further strengthened by a study among school children, investigating the attitude and behaviour towards reducing carbon emissions for a better health, with an element of hands-on activities using an energy-saving house to help them engage with the lesson and create a potential environment for learning (Lee *et al.*, 2013).

Apart from developing interest, this approach aims to reduce the complexity of some health-related information. Most of the diabetes-related information is complex for people with poor health literacy, for example, the elderly, the low-income population groups and the immigrants (Kickbusch *et al.*, 2013). Therefore, it is crucial for healthcare professionals to ensure that the language used to provide information for people with diabetes is suitable to them. Figure (40) lists the hands-on activities that are included in the MY DEUMI intervention manual.

Figure 40: List of hands-on activities in the MY DEUMI intervention manual.

- ❖ How to read food labels?
- ❖ Sugar game (self-count amount of sugar in food packages).
- ❖ Review of the pedometer.
- ❖ Keep calm and keep walking (a typical day worksheet to look for opportunities to improve daily routine movement or physical activity).
- ❖ Average steps per day.
- ❖ Daily foot inspection (step-by-step).
- ❖ Deep breathing exercises (step-by-step).

Figure (41) is an example of an appendix in the MY DEUMI intervention manual regarding the hands-on activity. Figures (42 and 43) are examples of how the facilitator could conduct the hands-on activities while delivering the MY DEUMI intervention. Figure (44) is an example of the "day-to-day food packages available in the Malaysian market" that is used to deliver the hands-on session, enhance the practicality, and promote understanding during the hands-on activity.

Figure 41: The appendix attached in the MY DEUMI intervention manual regarding the hands-on activity (How to read food labels).

Appendix 8: How to read food label

HOW TO UNDERSTAND FOOD LABELS?

BAGAIMANA UNTUK MEMAHAMI LABEL MAKANAN?

What to look for?

Apa yang perlu diperiksa?

If comparing nutrients in similar food use the per 100g column (Jika membandingkan makanan yang sama gunakan bahagian setiap 100g)

Sugar (Gula)

Try to avoid food with sugar content more than 15.0g per 100g (Elakkan makanan yang mengandungi gula lebih dari 15.0g setiap 100g)

Total fat (Jumlah garam)

Choose food with fat less 10g per 100g (Pilih makanan dengan kandungan lemak kurang 10g per 100g)

Saturated fat (Lemak tepu)

Aim for the lowest less than 3g per 100g (Sasarkan kepada jumlah paling rendah iaitu kurang 3g per 100g)

Nutrition Information (Maklumat Pemakanan)		
Serving size (saiz hidangan)	20g :5 piece (5 keping)	
Serving per package (hidangan setiap bungkus)	2	
	Per serve (satu hidangan)	Per 100g (setiap 100g)
Energy (Tenaga)	97kcal	486kcal
Carbohydrate (Karbohidrat)	13.8g	69.2g
Total sugar (Jumlah gula)	69	30.2g
Total fat (Jumlah lemak)	4.3g	21.4g
Salt/Sodium (Garam/Natrium)	0.069g	0.346g

Salt

Food less than 0.3g per 100g are low in salt (Makanan kurang daripada 0.3g setiap 100g adalah rendah garam)

- ❖ Be cautious of hidden sugar. For example, certain product stated no added sugar yet 10g of sugar were listed on the nutrition facts label. The reason for this is there are naturally occurring sugars present (lactose in milk).

Beri perhatian terhadap gula tersembunyi. Sebagai contoh, terdapat produk menjelaskan tiada gula tambahan namun 10g gula ada tersenarai dalam maklumat pemakanan. Ini disebabkan terdapat gula semulajadi (laktosa dalam susu).

- ❖ As a person with diabetes, you must be concerned with calories and carbohydrates especially simple sugars that would affect your sugar control.

Sebagai seorang penghidap diabetes, anda perlu mengambil berat tentang kalori dan karbohidrat terutamanya gula ringkas yang memberi kesan terhadap kawalan gula dalam darah anda.

Figure 42: The example in the MY DEUMI intervention manual of the “How to read food labels” activity in one of the hands-on sessions.

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Part 1: Food Labels

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Table with label
- * Flipchart
- * Sample of food with nutrient information

Table 11: Detailed lesson plan (Session 4: Part 1)

Time allocation	Section	Facilitator activity	Notes
60 min	Introduction	I would like to share with all of you the recommended amount of carbohydrate, sugar, fat, and salt per day. Is that okay?	Provide information see Key learning point 4.1.
	How to read labels?	Refer to handout given (How and when to read label?)	Distribute handout see Appendix 8: How to read food label. Provide information see Key learning point 4.2.
	Activity	Instruction: Please choose any of the food cartons on the table and read label using the label reader.	Display food carton on the table and distribute the label reader.
	Reflections	Explore: How this session would help you in your diabetes management?	Review and reflect using OARS where possible.

Figure 43: The example in the MY DEUMI intervention manual of the “Sugar game (self-count amount of sugar in food packages)” activity in one of the hands-on sessions.

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Reflections

Explore: How this session would help you in your diabetes management?

Review and reflect using OARS where possible.

Part 2: Sugar game

To conduct this session, you will need:

- * MY DEUMI manual
- * Table
- * Prepared tea spoon with sugar (1 teaspoon = 4 gram of sugar)
- * Sample of food and drink cartons with nutrient information

Table 12: Detailed lesson plan (Session 4: Part 2)

Time allocation	Section	Facilitator activity	Notes
60 min	Group activity	Instruction: Choose any food carton on the front table and calculate the number of teaspoons of sugar contained in the chosen food (based on the food label). Instruction: Display the amount of sugar counted for the sample of food that you've chosen.	Prepare food cartons, table and spoon with sugar.
	Reflections	Explore: What have you learned from this session?	Review and reflect using OARS where possible.

Figure 44: The examples and layout for the hands-on activities in the MY DEUMI intervention, showing the “how to read food labels and sugar game activity”.



5.8.3 Interactive activity

An innovative feature of this intervention compared with available diabetes education in Malaysia is the use of interactive activities for the participants in most of the sessions. The main objective of this approach is to engage the participants throughout the programme. Below is the list of activities included in the manual for the implementation of the MY DEUMI intervention:

- i. Quizzes such as understanding the glycaemic index through a quiz (see Figure 45 and 46), and stress level assessment: Depression, Anxiety and Stress Scale (DASS 21).
- ii. Group work activities such as matching food labels to the visual cards, goal setting discussions etc.
- iii. Motivational game: ‘Come on Six’ by Tom Jackson.
- iv. Sharing moment sessions by group members on their experiences of diabetes self-management.

Figure 45: An example of the appendix attached in the MY DEUMI intervention manual regarding the interactive activity (quiz) for session 2 (A sweet walk through time).



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Appendix 6: Glycaemic Index (GI) Quiz (Kuiz Indeks Glisemik(GI))

Question 1
How much white rice do you eat in one meal? (Barapa banyak nasi yang anda ambil pada setiap waktu makan?)

- 1 bowl (1 mangkuk)
- 2 bowl (2 mangkuk)
- 3 bowl (3 mangkuk)
- 4 bowl (4 mangkuk)

Question 2
Which one has higher GI? (Yang mana satu mempunyai kandungan GI yang lebih tinggi?)

Question 3
What's the GI for different types of rice? (Apakah nilai GI untuk berlainan jenis beras?)

Low GI: ≤ 55	Medium: 56-69	High: ≥ 70
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White rice (long grain/jasmine) (<u>beras putih</u>)	
	

Figure 46: An example of the appendix attached in the MY DEUMI intervention manual regarding the interactive activity (quiz) for session 2 (A sweet walk through time).

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Answer question 1.
One bowl about 200gm. This is what makes up your bowl of rice-percentage of appropriate daily recommended intake in brackets for average adults.

				
	1 BOWL	2 BOWL	3 BOWL	4 BOWL
Energy	280kcal (12%)	560kcal (24%)	840kcal (36%)	1120kcal (48%)
Carbohydrate	62.2g (21%)	124.4g (41%)	186.6g (62.2%)	248.8g (83%)
Protein	5.6g (9%)	11.2g (17%)	16.8g (27%)	22.4g (35%)
Fats	1g (2%)	2g (3%)	3g (5%)	4g (9%)
GI	79	79	79	79
Glycaemic load	37	74	114	148

White rice has high GI of 79. What does that mean?

GI : is a measure of how food containing carbohydrates raises blood sugar levels
: ranges from 0 to 100 represent how quickly a person's blood sugar level rises after eating food containing carbohydrate
: GI above 70 = high
: GI below 55 = low

Answer question 2.

	
GI : 72 Glycaemic load : 4	GI : 63 Glycaemic load : 22

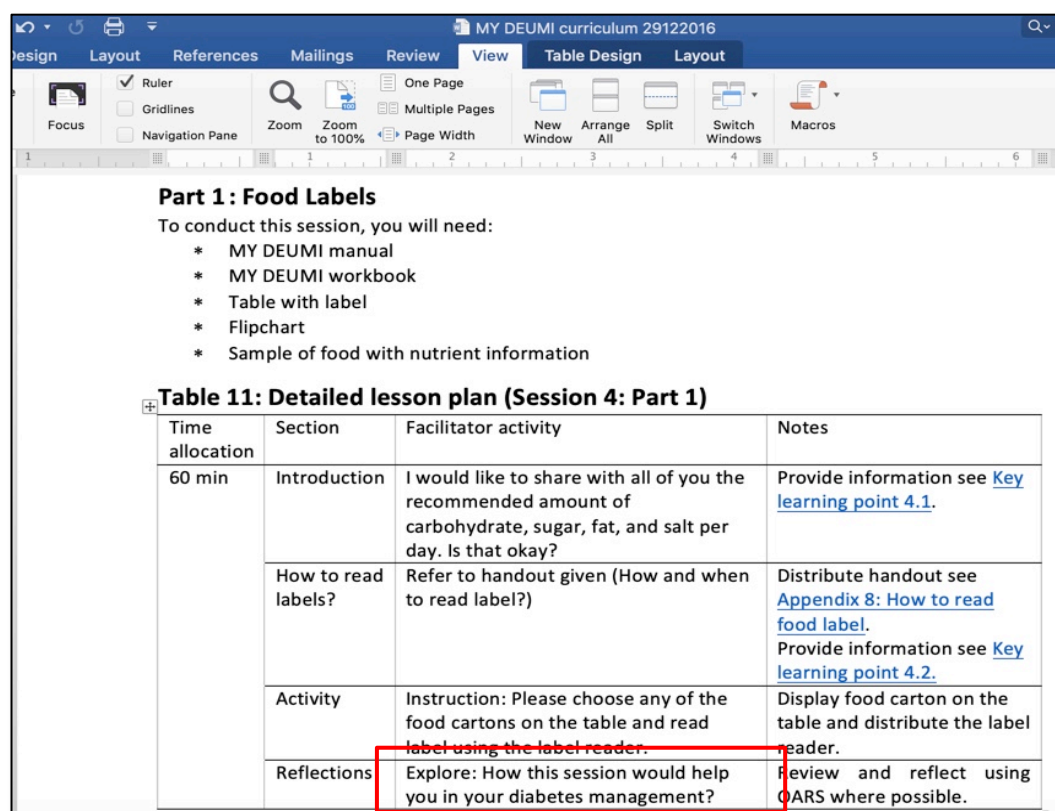
Not only GI is concern it also has to do with glycaemic load.
Watermelon has high GI of 72 but mostly water and has low GL of 4
In comparison coke low GI but high carbohydrate the GL is 5 times watermelon

5.9 Evaluation strategies for the intended outcome

Generally, the assessment of educational interventions and learning is reciprocal, and aims to evaluate the quality of the instructor or facilitator, the curriculum or manual, and the learners. However, an assessment does not entirely reflect the success of learning due to factors such as the learners' commitment and motivation. The process of evaluation acts as a means for the educators to reform, revise and refine.

Assessment in the health education field is challenging due to the impracticality of transforming the evaluation process in the form of quantitative grades for the learners (Clark, 2011). A scoping review suggested that the formative assessment model is pragmatic and sensible to enhance the learning environment, as well as to improve the skills and competency of the health educator (Koster and Wing, 2014). Formative assessment is useful to indicate the efficiency of the delivery session and to evaluate the learner's performance during the learning process (Sadler, 1989). It is an on-going assessment conducted while delivering the curriculum, usually at the end of each session, and it can be in the form of simple quiz, reflection sessions, sharing moments or discussions. In the MY DEUMI intervention, the researcher (the facilitator) included a reflective session mainly at the end of sessions (see Figure 47), to gather feedback and evaluate the understanding of the participants. This helps the facilitator to be more flexible, and improve any ineffective delivery sessions or information.

Figure 47: An example of a reflection session at the end of hands-on activity in the MY DEUMI intervention manual.



Part 1: Food Labels

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Table with label
- * Flipchart
- * Sample of food with nutrient information

Table 11: Detailed lesson plan (Session 4: Part 1)

Time allocation	Section	Facilitator activity	Notes
60 min	Introduction	I would like to share with all of you the recommended amount of carbohydrate, sugar, fat, and salt per day. Is that okay?	Provide information see Key learning point 4.1 .
	How to read labels?	Refer to handout given (How and when to read label?)	Distribute handout see Appendix 8: How to read food label . Provide information see Key learning point 4.2 .
	Activity	Instruction: Please choose any of the food cartons on the table and read label using the label reader.	Display food carton on the table and distribute the label reader.
	Reflections	Explore: How this session would help you in your diabetes management?	Review and reflect using QARS where possible.

5.10 Intervention content

Prior to the commencement of the MY DEUMI content, an introductory session was included. The two introductory sessions generally aimed to: (i) explain the overview of the programme (provide an opportunity for any question from the participants); (ii) assess the participants' readiness; and (iii) as an ice-breaking exercise between the group members, and to build rapport between the participants and the facilitator. Following the introductory sessions, the intervention, which consists of 11 sessions with a total of 10 hours, was conducted as either a 2-half-day course or a 3-night weekday course. The content of the sessions is as follows:

Introductory session one (1)

Parts	Content
Icebreaking	<ul style="list-style-type: none"> • Ice breaking game for the participants to get to know each other, and explaining of the ground rule as well as the programme outline.
Conclusion	<ul style="list-style-type: none"> • Readiness assessment through the “Are you ready checklist”.

Introductory session two (2)

Parts	Content
Sharing moments	<ul style="list-style-type: none"> • Discussion on the risk factors of T2DM.
Elicit change talk	<ul style="list-style-type: none"> • Discussion on the benefits of lifestyle change.
Evaluation	<ul style="list-style-type: none"> • Knowledge assessment through diabetes knowledge questionnaire.

Session 1: What is diabetes?

Parts	Content
Elicit understanding of T2DM	<ul style="list-style-type: none"> • Discussion on normal food digestion through quiz. • Discussion on insulin regulation. • Sharing of complications experiences by the participants.
Eliciting change talk	<ul style="list-style-type: none"> • Discussion on the reasons to reduce complications among the participants.
Goal setting	<ul style="list-style-type: none"> • Discussion on the effective goal setting techniques by elaborating the important characteristics of a goal.

Session 2: Eating in balance: A sweet walk through time.

Parts	Content
Eliciting the primary goal of self-care (glycaemic control)	<ul style="list-style-type: none"> • Discussion on healthy eating practice (What to eat and drink more). • Discussion on low glycaemic index diet through quiz and the method to reduce it — carbohydrate intake (the healthy plate model).

Session 3: Diabetes medicine guide

Parts	Content
Available medicine	<ul style="list-style-type: none">• Sharing of individual prescriptions by the participants.
Types of diabetes medicine	<ul style="list-style-type: none">• Discussion regarding the types of diabetes medicine and the possible side effects.• Discussion regarding the fear of insulin by reflecting its benefits in term of blood sugar control and in delaying complications.

Session 4: Keep calm and let's play

Parts	Content
Food labels	<ul style="list-style-type: none">• Discussion on the recommended amount of carbohydrate, sugar, fat and salt intake per day• Learning how and when to read the food labels on the displayed food cartons.
Sugar game	<ul style="list-style-type: none">• Calculation of the number of teaspoons of sugar contained in chosen food cartons and reflection of the outcome of the activity by the participants.

Session 5: Let's move! To stay healthy and lose weight

Parts	Content
Building confidence	<ul style="list-style-type: none">• Sharing of successful weight loss experience by the participants
Introduce walking as part of physical activity	<ul style="list-style-type: none">• Discussion on the recommended number of steps a day
Eliciting change talk	<ul style="list-style-type: none">• Participants' discussion with a partner on the reason to choose walking as a form of exercise.

Session 6: Keep calm and keep walking!

Parts	Content
Broadening perspectives	<ul style="list-style-type: none">• Discussion on typical daily activities and work that provide opportunities to increase the number of steps in a day.
Activity	<ul style="list-style-type: none">• Reflections by the participants on the amount of calories burned through a simple exercise.
Goal setting	<ul style="list-style-type: none">• Discussion on the target number of steps in a day for the coming week.

Session 7: Diabetes foot

Parts	Content
Foot assessment	<ul style="list-style-type: none">• Participants' diabetes foot ulcer risk assessment.
Activity	<ul style="list-style-type: none">• Learning to carry out daily foot inspection (a step-by-step guide).

Session 8: Dealing with diabetes

Parts	Content
Realising potential	<ul style="list-style-type: none">• Identification of participants' post diagnosis and current feelings.
Activity	<ul style="list-style-type: none">• Group activity among participant shares their reflection through the motivational game. (can we rephrase this as 'Reflection sharing by the participants in a group activity involving a motivational game.'?)
Stress level assessment	<ul style="list-style-type: none">• Identification of participants' stress level through the Depression, Anxiety, Stress Scale (DASS 21) test.
Activity	<ul style="list-style-type: none">• Deep breathing exercise lesson as part of stress management for the participants.

Session 9: Complementary and alternative medicine (CAM)-Herbal medicine

Parts	Content
Exploring values	<ul style="list-style-type: none"> • Identification of complementary medicine usage among participants.
	<ul style="list-style-type: none"> • Reflection on the importance of complementary medicine in their disease management by the participants.
Broadening perspectives	<ul style="list-style-type: none"> • Discussion on the mechanism and potential side effects of the most used herbal medicine in type 2 diabetes mellitus management.

Session 10: Relapse prevention

Parts	Content
Broadening perspective	<ul style="list-style-type: none"> • Discussions and reflections on the stories regarding lapses and relapse.
Activity (Inspiration and motivation)	<ul style="list-style-type: none"> • Reflection and identification of each member's positive qualities from their shared experiences.
Confidence ruler (Eliciting change talk)	<ul style="list-style-type: none"> • Identification of participants' current level of self-confidence

Session 11: Yes, I can do it!

Parts	Content
Review and reflect	<ul style="list-style-type: none"> • Reflection and discussions in pairs on the whole programme and its most beneficial activity
	<ul style="list-style-type: none"> • Briefing regarding follow-up activities and the 12-week glycaemic control review (telephone reminder).

5.11 Face validity

Face validity of the manual was conducted with four experts in T2DM and chronic disease management. The first panel was Dr Kirsty Winkley: a diabetes nurse and an active researcher in developing and evaluating complex interventions using enhanced psychological therapy, to improve diabetes control and depression. The second panel consisted of 3 health professionals in the Ministry of Health (MOH) Malaysia, namely; (i) Dr Jaidon Romli a medical consultant and chief of a primary care centre; (ii) Ms Bareah Jaafar a diabetes nurse educator in a primary care centre; and (iii) Mrs Fathiah Hani Ismail, a senior dietitian in a general hospital who is involved in chronic disease management. The discussion focused on the practicality, accuracy, duration, evidence base and language. Table (5.3) is the checklist employed by all the panels to give their constructive feedbacks for further improvement of the manual, which was modified and adapted from the (NHS Education for Scotland, 2009) before it was being implemented with the participants.

Table 5.3: Checklist for the face validity of the manual.

Underlying principle	Suggested areas to be considered	Compliance (please tick)		notes
		Yes	No	
Activities planned in the programme is based on local (Malaysian) information, practice and contexts.				
The activities planned in the programme are holistic and integrated.				
The manual content is developed using appropriate language and jargon.				
The manual approach can be adapted to meet the needs of the participants.				
The manual content is aligned with the ministry policies.				
The manual content supports the language and literacy of the participants.				
Opportunities for feedback and review are provided to the participants.				
Sources of all evidence in the manual are correctly referenced.				
The manual content developed is aligned with the adult learning principles (active and learner-centric).				
The content of the programme addresses the needs of participants' cultural background and language proficiency.				

Modified and adapted from the (NHS Education for Scotland, 2009).

Necessary amendments were made based on the expert panel's comments and suggestions, and the final manual was assembled for the researcher to proceed with the feasibility study. Table (5.4) is the summary of feedback on the MY DEUMI written curriculum from the panellists. The intervention manual is included in Appendix A.

Table 5.4: Summary of panellists' feedback on MY DEUMI written curriculum.

Feedback source	Found useful	Suggested improvements	Changes as a response to the feedback
Physician's feedback	<ul style="list-style-type: none"> • Holistic approach and a complete guide for people newly diagnosed • Interactive (hands-on activities and visual aids) 	<ul style="list-style-type: none"> • To simplify the explanation regarding the pathophysiology, which occurs in the body of people with T2DM 	<ul style="list-style-type: none"> • Added more visual aid and quiz to ensure participation.
Nurse's feedback	<ul style="list-style-type: none"> • The quiz and interactive game are interesting approach rather than a full lecture. • More discussions to allow for 2-way communication and create a casual environment 	-	-
Dietitian's feedback	<ul style="list-style-type: none"> • Reflection sessions allow for sharing of information and experiences. • Complete and comprehensive guide based on the topic listed 	<ul style="list-style-type: none"> • Ensure a variety of products (brand) of the food cartons or packages used for the hands-on activities to reduce bias (Ministry policies). 	<ul style="list-style-type: none"> • Prepared different brands for the same item, as per advised.

5.12 Summary

This brief chapter explains the details of the MY DEUMI intervention development process. It discusses the scoping review and how available resources were compiled for manual development, followed by the step-by-step process to produce the intervention manual. Using group MI as the delivery approach, the researcher discussed the process involved and outlined in the written manual, and the way the unique features of hands-on and interactive activities were used to present the content of the intervention. After the manual intervention was fully developed, it was evaluated in a small feasibility study, which will be discussed in the next chapter.

Chapter 6 : Feasibility study of the *Malaysian Diabetes Education Intervention using Motivational Interviewing (MY DEUMI)* for people newly diagnosed with type 2 diabetes mellitus.

6.1 Chapter scope

This chapter describes the overall method used to assess the acceptability and feasibility of the MY DEUMI intervention. The first section presents the rationale and study aims. The second section reports the methodology used, research design, recruitment process, outcome measurement, process evaluation and data analysis. The third section outlines the quantitative findings and qualitative feedback from the participants (exit interviews). Lastly, the fourth section discusses the study outcomes, strengths, limitations and conclusions.

6.2 Introduction

Diabetes is a common progressive disease and one in seven Malaysian adults are diagnosed with diabetes (Institute for Public Health, 2011). DSME promotes and supports self-management among people with T2DM to optimise lifestyle modification, improve metabolic control, improve quality of life and delay acute or chronic complications. However, there is a lack of group DSME available in Malaysia and psychoeducational approaches are not generally used. Therefore, the researcher sought to develop and pilot MY DEUMI, a group-based diabetes self-management psychoeducational intervention tailored to Malaysian culture. The rationale for developing this psychoeducational intervention for Malaysians newly diagnosed with T2DM are as listed below:

1. High prevalence of T2DM and the limited availability of DSME in Malaysia (see Chapter 1 and 2).
2. Poor glycaemic control due to poor self-management (see Chapter 3).
3. Early onset of T2DM in Malaysia (see Chapter 1).
4. Patient empowerment and motivation for self-management (see Chapter 4 and 5):
 - Self-management was recently recommended as an alternative approach for diabetes management. Theory-driven and psychological techniques are the major component of the MY DEUMI intervention, to empower people with diabetes towards effective self-management and promote self-efficacy
5. Group-based approach (see Chapter 4 for discussion):
 - Group-based approaches can be helpful to patients and are potentially cost-effective. However, whether they are acceptable in Malaysian setting is unknown.

6.3 Research Aims

The main aim of this study is to determine the feasibility and acceptability of group structured diabetes education involving motivational interviewing, the MY DEUMI programme, among Malaysians with newly diagnosed T2DM. The subsidiary aim is to determine whether people who attend the MY DEUMI programme have improved biomedical outcomes at around 12-week post-course.

Specific objectives included are to:

1. Assess the recruitment, follow up, and completion rates.
2. Determine whether group diabetes education enhanced motivational interviewing (MY DEUMI programme) can improve biomedical outcomes, self-efficacy in diabetes management and diabetes self-management practice.
3. Investigate the acceptability of the programme through qualitative interviews
4. Identify facilitators and barriers faced by the researcher.

All of which are important to be determined ahead of MY DEUMI being tested in a larger trial. It was decided that the intervention could be considered feasible if the following objectives were met:

- i. At least 20 participants were recruited.
- ii. Eleven sessions were conducted.
- iii. Dropout rate of no higher than 30%.
- iv. Completion rate of at least 50%.
- v. There were no major logistic issues affecting the commencement of each of the MY DEUMI session.

6.3 Ethical approval

The study was granted an ethical approval by the Psychiatry, Nursing and Midwifery (PNM) Research ethics subcommittee (RESC) at King's College London HR-15/16-2009 (see appendix B), and from the Medical Research and Ethics Committee (MREC) Ministry of Health Malaysia NMRR-15-2200-27537 (see appendix C). The potential ethical issues considered are listed below:

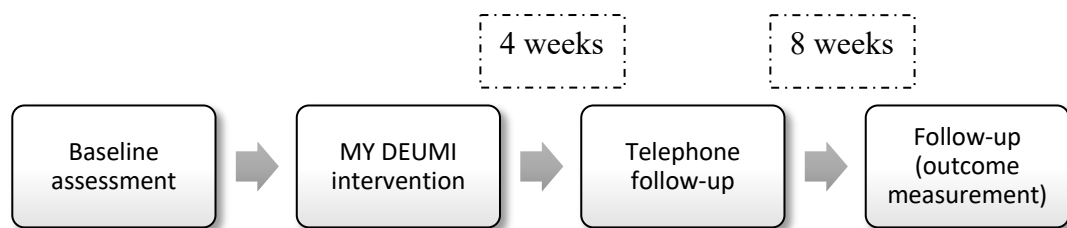
1. Voluntary participation: The researcher emphasised to potential participants that participation is entirely voluntary and may be discontinued at any time. In addition, reminder text messages have given participants ample time to reconsider their participation.
2. Risk consideration: From the exclusion criteria, only participants who were physically and cognitively fit were invited to participate, and were required to give their consent independently. The researcher did not anticipate there would be any disadvantage of participating in the study. The education sessions were based on the information regarding Type 2 Diabetes Mellitus (T2DM), on how eating more healthily, increasing physical activity, gradual and sustainable weight loss, may bring health benefits; and were delivered using a motivational interviewing approach.
3. Confidentiality: Only the researcher has the access to participants' personal data, which was anonymised using an identification (ID) code. The information sheet and consent form highlighted that the research data would be treated in a confidential manner, and handled in accordance with the General Data Regulation Protection (GDPR) and Data Protection Act 2018.

6.4 Methods

6.4.1 Research design

This was a small feasibility study, in which a single arm group pre-post design was implemented. The intervention involved within-group comparisons over two-time frames (pre-intervention/baseline and at 12-weeks post-intervention). Figure (48) represents the study timeline from the baseline assessment and to the final follow-up. Outcomes were measured for each participant, and the analysis focused on the effect of treatment using a repeated measure design.

Figure 48: The MY DEUMI intervention timeline.



6.4.2 Location and setting

The study was conducted at two local primary care clinics (*Klinik Kesihatan Tampoi* and *Klinik Kesihatan Tebrau*) in Johor, which is the second largest populated state in the southern peninsular of Malaysia. The other setting used was three community centres which are called 'Rukun Tetangga' or *KRT*, namely *KRT Pasir Putih*, *KRT Bendahara* and *KRT Taman Universiti*, participated by community members in the neighbourhoods. Seminar rooms were used to deliver the intervention at all the designated locations.

6.4.3 Study population

The case definition used included adults aged 18 years or more diagnosed with T2DM based on the clinical practice guidelines (CPG) for management of T2DM (Ministry of Health Malaysia, 2015).

The inclusion criteria are:

- i. Diagnosed with T2DM for less than 5 years at the time of recruitment.
- ii. Fluent in conversational Malay language.
- iii. Citizens of Malaysia.

The exclusion criteria are:

- i. Type 1 diabetes mellitus or other types of diabetes.
- ii. Severe chronic conditions such as heart failure, renal failure or liver cirrhosis.
- iii. Severe mental illness such as schizophrenia, bipolar disorder, severe depression.
- iv. Cognitive impairment.
- v. Unable to move independently or needing assistance with daily activities.
- vi. Women who are pregnant.

6.4.4 Procedure for recruitment

The methods of recruitment and follow up are described below. The recruitment took place between end of November 2016 and mid-January 2017. Two methods were used: (i) Invitation from the physician in the primary care clinic; (ii) Recruitment via the head of the community centres. The second route of recruitment was added at a later stage because only 31% (14 out of 45) participants who were invited, were interested in participating, and only 8 participants actually attended the planned sessions at the primary care clinics.

The main reason given for not participating was the inconvenient timing of the sessions, which was due to work commitments or babysitting their grandchildren. The seminar room in the primary care clinic was only available from 9am to 5pm on weekdays, and only for certain days in a week for example only due to other routine clinic activities.

Whereas, recruiting through the community centres increased the response to 75%, as the researcher was able to offer sessions in the evenings and over the weekend, because the community facilities are open daily from morning to midnight. Even though there were other routine activities in the community centres, such as health screening programmes, mother and baby groups, as well as pensioner group activities, there was more flexibility there plus the advantage of longer opening hours compared to the primary care clinics.

Recruitment procedure from the primary care clinic.

Potential participants were identified with the help of a diabetes nurse through assessing the primary care clinic database. Formal invitations including the information sheet (see Appendix D) and consent form (see Appendix E) were distributed through postal mail to all potential participants. The researcher then contacted all the potential participants who were interested in the programme and asked them to return the consent form. The date and venue of the sessions were then provided to the list of participants who agreed to be included. Baseline data was collected prior to the MY DEUMI sessions. Figure (49) illustrates the flowchart of recruitment from the primary care clinic.

Recruitment procedure from the community centre.

An officer from the district health department provided a list of gatekeepers (head of the ‘Rukun Tetangga’) for community centres around the city of Johor Bahru. There were six community centres identified in total, namely *KRT Skudai Kiri*, *KRT Taman Tampoi Indah*, *KRT Tiram*, *KRT Pasir Putih*, *KRT Bendahara*, and *KRT Taman Universiti*.

Initial briefing regarding the programme was given by the researcher to the community centre gatekeepers and following this, three community centres agreed to proceed with the intervention sessions, while the others had tightly scheduled activities over the school holiday period. The next stage involved the recruitment of potential participants who were identified by the community centre leaders, and a special meeting was convened to answer any questions from potential participants with the researcher in attendance.

At the same time, the information sheets and consent forms were distributed by the researcher and signed by the participants who intended to participate following the briefing and discussion session. The dates and times of the MY DEUMI sessions were finalised according to participants’ convenience and availability. Baseline data was gathered prior to the delivery of the intervention and Figure (50) shows the flowchart of recruitment from the KRT.

Meeting with the physicians and diabetes nurses (primary care clinics) and heads of the ‘Rukun Tetangga’ for organisational permission prior to the recruitment.

Formal meetings between the researcher and each of the organisation’s representatives were held to outline the background and rationale for the intervention, eligibility criteria for participants, as well as details of the MY DEUMI sessions and procedures.

Potential barriers for the implementation as well as the plans to address them were also discussed in the meeting. The main barrier anticipated by the partner organisations was the participation rate. Therefore, a reminder text message was sent to the participants a week and a day before any sessions to maximise attendance.

The delivery of the MY DEUMI sessions

The researcher facilitated the delivery of the MY DEUMI intervention programme, while the diabetes nurse in the primary care clinics and leader of the community centres assisted with the logistic arrangements. After each completed session, reminders for the next session were sent to all participants along with a summary of the session through a social media application for smart phones. Further questions were also discussed through the same channel.

Follow-up

Four-weeks after the completion of the MY DEUMI sessions, participants received a follow up telephone call from the facilitator (the researcher), to monitor their progress on the day-to-day diabetes self-management, as well as to answer any questions or discuss any challenges and how to address them. Twelve weeks post-completion of the MY DEUMI intervention, an appointment was arranged to measure glycaemic control, body weight and for the participants to complete a validated questionnaire (Diabetes Management Self-Efficacy Scale United Kingdom and Diabetes Self-Management Questionnaire).

Figure 49: The recruitment flowchart at the Primary care clinics.

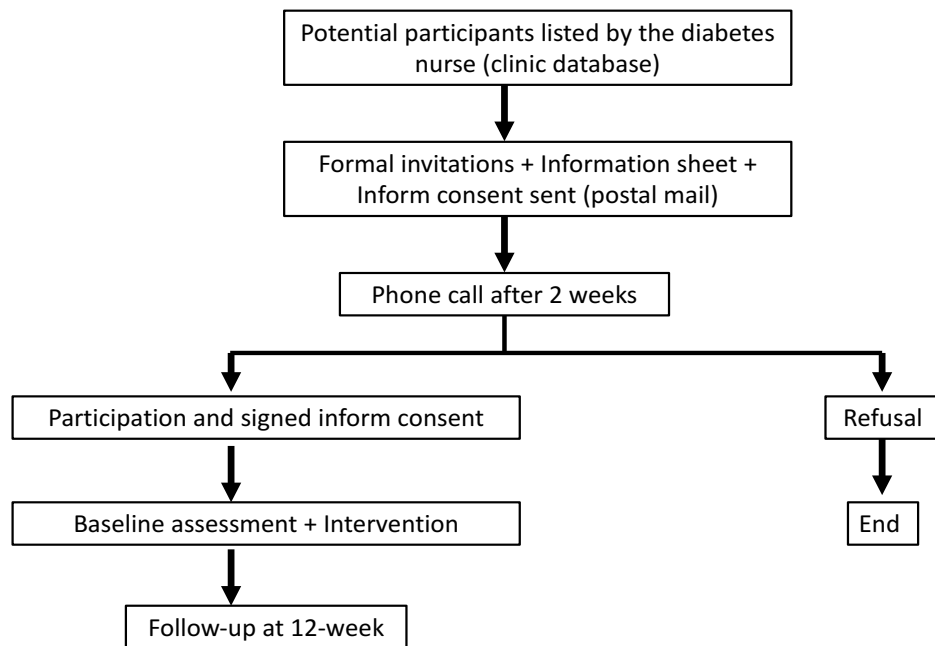
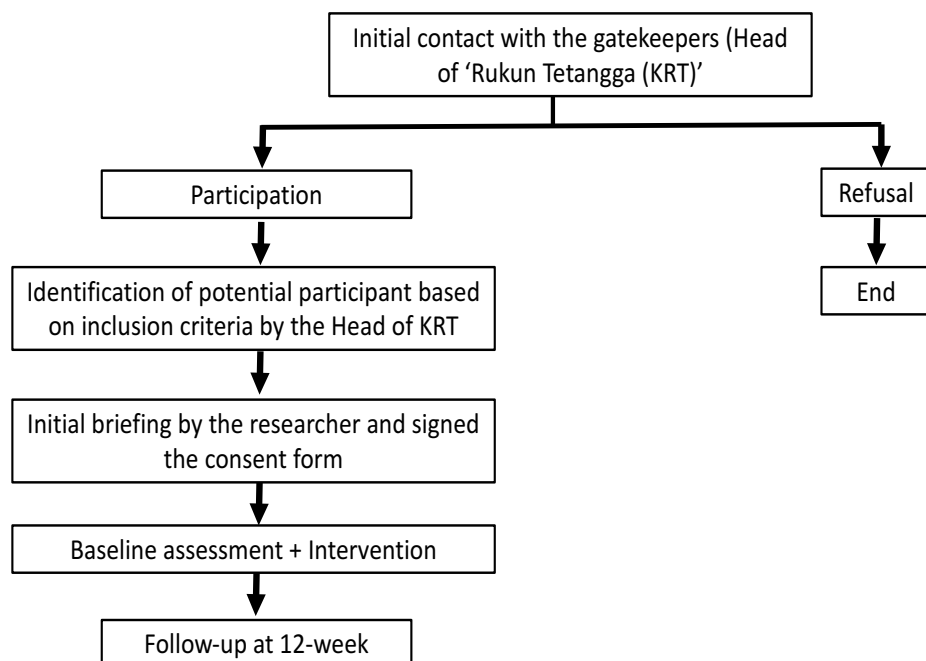


Figure 50: The recruitment flowchart at the community centres (KRT).



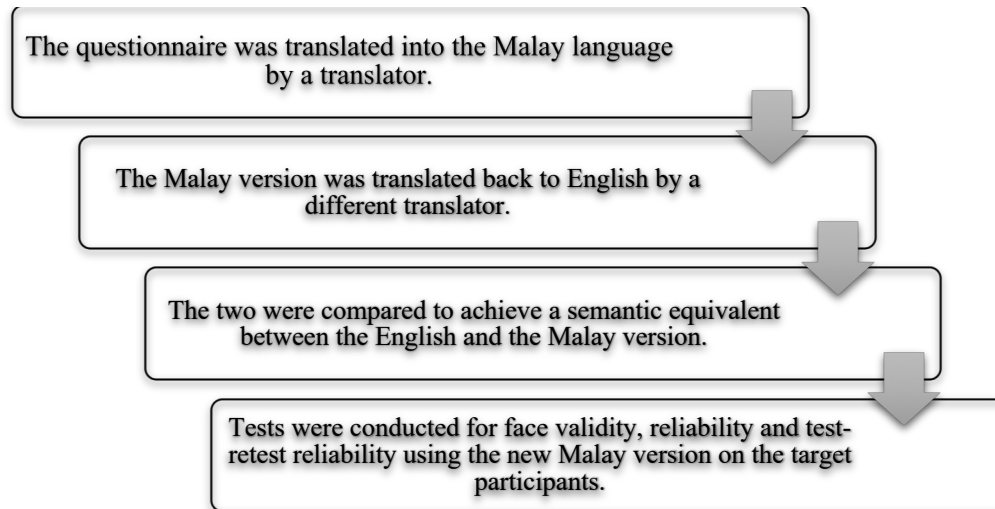
6.4.5 Outcome measures

The primary outcomes were changes in glycaemic control, as measured by the fasting plasma glucose (FPG) level (mmol/L), body weight in kilogrammes, and the body mass index (BMI) (kg/m^2) from the baseline assessment to 12-week follow-up. Secondary outcomes assessed were the difference in participants' self-efficacy in diabetes self-management, and self-care level using a self-report questionnaire.

Self-efficacy and diabetes self-management were measured using the Diabetes Management Self-Efficacy Scale United Kingdom (DMSES UK) validated by (Sturt, Hearnshaw and Wakelin, 2010), and the Diabetes Self-Management Questionnaire (DSMQ) respectively. The DMSES UK was originally developed by the International Partners in Self-management and Empowerment (IPSE) in the Netherlands (Bijl, Poelgeest-Eeltink and Shortridge-Baggett, 1999), and is deemed reliable with a Cronbach's alpha value of 0.89. Diabetes self-management among participants was measured using 16 items of the DSMQ (Schmitt *et al.*, 2013). This has a good overall internal consistency, with a Cronbach's alpha value of 0.84.

The questionnaire was translated to the Malay language according to the published guidelines (Maneesriwongul and Dixon, 2004). The minimum standard is back-translation with monolingual testing to ensure the original elements can be measured in cross-cultural research. Back translation and monolingual tests were used by the researcher to validate the translated questionnaire (Hawkins and Osborne, 2012). The method involved the following process illustrated in Figure (51).

Figure 51: The process involved during the translation of the questionnaire.



The translated DMSES UK achieved a good overall internal consistency (Cronbach's alpha) of 0.94. The translated DSMQ attained an acceptable alpha value of 0.7 (Bland and Altman, 1997). Further revision of the items was suggested for this translated version, to increase the validity and accuracy in the data interpretation (Tavakol and Dennick, 2011), if it were to be used in any future study.

6.4.6 Exploratory process measure (quantitative and qualitative approaches)

According to the Medical Research Council (MRC) framework (Moore *et al.*, 2015), a process measurement is recommended when developing complex interventions. The term process measure or formative evaluation are used interchangeably, and are used to examine the quality of an intervention (Israel *et al.*, 1994). This exercise is an essential part in the process of developing and evaluating complex interventions, especially before replication in a larger trial. It also works as a post-mortem framework to evaluate the success of the intervention, and how it will affect outcomes (Bouffard, Taxman and Silverman, 2003).

Steckler and Linnan, (2002), suggested that at least four elements should be included in any process evaluation, namely: dose delivered; dose received; reach; and fidelity. Meanwhile, Saunders, Evans and Joshi, (2005), proposed seven elements namely: recruitment; reach; dose delivered; dose received (exposure); dose received (satisfaction); fidelity and context to guide the process evaluation after the implementation of any intervention. Table (6.1) describes the process measure that were used for the evaluation of the MY DEUMI intervention.

Table 6.1: Details regarding process measure by Saunders, Evans and Joshi, 2005.

Measures	Description
Recruitment	Procedure executed to approach and promote participation from any individual or organisation.
Reach	This component is usually measured by attendance or registered participants that took part in the intervention.
Dose delivered (completeness)	The number of sessions provided to the participants from the total sessions outlined in the intervention manual.
Dose received (exposure)	The extent to which participants who attended the intervention, were actively involved, interacted and utilised the materials that were given or recommended.
Dose received (satisfaction)	Participants' positive and/or negative feedback regarding the intervention.
Fidelity	Explains the extent to which the intervention was delivered according to the intervention manual
Context	Environmental factors that may influence the intervention delivery process or the study outcomes.

Adapted from (Saunders, Evans and Joshi, 2005).

Process evaluation questionnaire

A process evaluation questionnaire can be used to explore the procedure and process (the who, what, when and how), as well as the programme outputs of an intervention (Centers for Disease Control and Prevention, 2009). The aim is to provide core evidence for areas where the intervention needs improvement in order to achieve the expected outcomes and allows for an immediate change for a smooth continuous implementation. The stakeholders involved in intervention development should convene and brainstorm relevant questions that might impact the running and achievement of the intervention (Centers for Disease Control and Prevention, 2008).

The Likert scales are widely used to measure the attitudes of individuals, by seeking views and reactions to a series of statements regarding a topic or an issue, and the extent to which they agree or disagree with them (Bowling, 2002,pg 316). Therefore, the researcher outlined six domains measured using the Likert scales for the participants to complete to evaluate the MY DEUMI intervention, namely: facilitator; topics; materials; time management; and objectives. The five-point Likert scale (Level of quality) was used in the evaluation (Vagias, 2006). An additional domain was included to assess the likelihood of lifestyle change. The evaluation questionnaire was distributed to the participants to be completed after the completion of the MY DEUMI intervention sessions or during the follow up (see Appendix F).

Exit interviews

A qualitative exploration (semi-structured exit interviews) was used as part of the process evaluation to understand the intervention outcomes from the participants' perspectives. The MY DEUMI participants were invited to be interviewed to share their opinions and views regarding the intervention. The objectives of the semi-structured interviews are to: (i) describe the programme processes; (ii) explore participants' experiences and the outcome; and (iii) evaluate the differences in the programme implementation at different sites.

An interview guide was developed based on literature review and clinical experience as shown in Figure (52). The interviews covered participants' hopes, expectations for self and family, possible challenges and individual opinions for improvement of the programme. Verbal consent was obtained prior to the interview session. All interviews were conducted face-to-face in either Malay language or English language, depending on their preference and later transcribed verbatim. The transcripts were analysed using the qualitative thematic analysis and the data was organised using the Nvivo version 11.0 software.

Figure 52: Interview guide to evaluate the implementation of the programme (exit interview).

1. Why did you join MY DEUMI (*Prompt, as necessary: (i) What did you hope to achieve by joining MY DEUMI; (ii) What benefits did you expect to receive as a result of participating in MY DEUMI (in term of knowledge or skills).*
2. In what way(s) has MY DEUMI met your expectations and/or needs?
3. In what way(s) has MY DEUMI failed to meet your expectations and/or needs?
4. In what way(s) do you think the new knowledge products or resources from MY DEUMI that you have been able to use will benefit individuals, family and community in general? (*Prompt, as necessary: (i) Do you think you will (or already have) benefit on an individual or personal level from the new knowledge products or resources? If so, please explain. (ii) Can you think of in which ways your family will (or already has) benefit from the new knowledge products or resources? If so, please explain. (iii) Do you think the new knowledge products or resources will (or already have had) an impact on the public or community? If so, please explain.*
5. In your opinion, what are the most important outcomes or benefits that have resulted from MY DEUMI?
6. How would you rate the overall success of MY DEUMI using a scale from one to ten, where one is a complete failure and ten is a total success? (*Prompt, as necessary: (i) Why?*
7. In your opinion, how effective MY DEUMI has been in the following:
 - i. Building a self confidence among participants (explain why and how).
 - ii. Improving information and knowledge among participants (can you expand a little bit on this).
 - iii. Enabling the application of knowledge to practice or diabetes self-management (explain why and how)
8. Are there other factors or circumstances that you think contributed to the success (or failure) of MY DEUMI? Please explain.
9. Did you experience any challenges or barriers (that kept you from participating in the MY DEUMI)? If so, can you elaborate more and give an example.
10. Can you think of anything MY DEUMI could do differently to address the challenges or barriers that might keep people from participating fully?

6.4.7 Data analysis

The data for each outcome measure was entered into Excel spreadsheets. All data was examined for completeness before they were exported to the Statistical Package for the Social Sciences (SPSS) Version 23 software for analysis. The aim of the study is to investigate the difference in glycaemic control, body weight, as well as the improvement in self-efficacy and self-care practice at 12-week post intervention.

Descriptive statistics were used to describe the outcome measures pre-and post-intervention. Then, the data was analysed using the paired t-test and the Wilcoxon-signed rank test in order to analyse the difference in the outcome measure within the groups. Paired t-test was conducted to determine whether there was an improvement in the fasting blood glucose level for participants in receipt of the MY DEUMI intervention. If the data were skewed or for ordinal data, the Wilcoxon signed rank test was performed.

Following statistical testing, the magnitude of the effect was calculated using a standardised effect size, to determine the impact of the MY DEUMI intervention (Sullivan and Artino, 2013). Describing results in terms of magnitude is more convincing as the p value shows whether the intervention is effective statistically, and the effect size explains the degree of effect on the people involved (Cohen, 1990). According to Rosenthal (1994), effect sizes are divided into two families; the d family (consists of standardised mean difference), and the r family (measures the strength of association) (Rosenthal, 1994).

The effect size for the fasting blood glucose was calculated using the formula below as recommended by (Lakens, 2013) (refer to Table 2 for the range value):

$$\text{Cohen's } d = \frac{M_{diff}}{\frac{SD_1 + SD_2}{2}}$$

Meanwhile, the effect size for the BMI, self-efficacy and self-care practice were calculated using the formula below (refer to Table 2 for the range value):

$$r = z \text{ value} / \sqrt{N} \text{ (number of observations over the two-time points)}$$

Table 6.2: The range of effect size (Cohen's d and r).

Effect size/ Range	Cohen's d	r
Small	0.2	0.1
Moderate	0.5	0.3
Large	0.8	0.5

Adapted from (Cohen, 1988).

6.5 Results

The results section is divided into four sub-sections. First, the demographic characteristics of the participants. The second section describes the results of the feasibility testing of the MY DEUMI intervention. Assessment was made on the recruitment, reach, dose delivered, dose received and fidelity (Steckler and Linnan, 2002). Next, the descriptive statistics of the outcome measure and the preliminary effects of the MY DEUMI intervention are presented. Finally, the fourth section details the acceptability of the MY DEUMI intervention, which was evaluated using qualitative semi-structured interviews and assessing participants' satisfaction via the evaluation questionnaire.

6.5.1 Demographic characteristics

Thirty adults recently (at least 5 years of diagnosis) diagnosed with T2DM were recruited. Table (6.3) displays the demographic characteristics of the study participants.

Table 6.3: The demographic characteristics of the MY DEUMI participants at baseline (N=30).

		Range	N (%)	Mean (SD)
Age (years)		35-72		57.03 (9.78)
Gender	Male		7 (23)	
	Female		23 (77)	
Marital status	Married		24 (80)	
	Widower		6 (20)	
Education	Primary		8 (27)	
	Secondary		16(53)	
	Diploma		5 (17)	
	Bachelor		1 (3)	
Duration of diagnosis (months)	< 12 months		6 (20)	
	≥ 12 months		4 (13)	
	≥ 24 months		5 (17)	
	≥ 36 months		4 (13)	
	≥ 48 months		2 (7)	
	≥ 60 months		9 (30)	
Co-morbidity disease	Hypertension		20 (67)	
	Cardiovascular problem		2 (7)	
	Hypercholesterolemia		19 (63)	
Pharmacology management	Oral anti-diabetic agent		28 (93)	
	Insulin		6 (20)	
Complementary medicine user	Herbal medicine		10 (33)	

6.5.2 Feasibility of MY DEUMI

The main objective of the MY DEUMI intervention is to determine the feasibility of the intervention, and to explore if a larger trial is possible. In summary, the overall feasibility criteria were met, although several modifications would be required to improve its delivery.

This study demonstrated that:

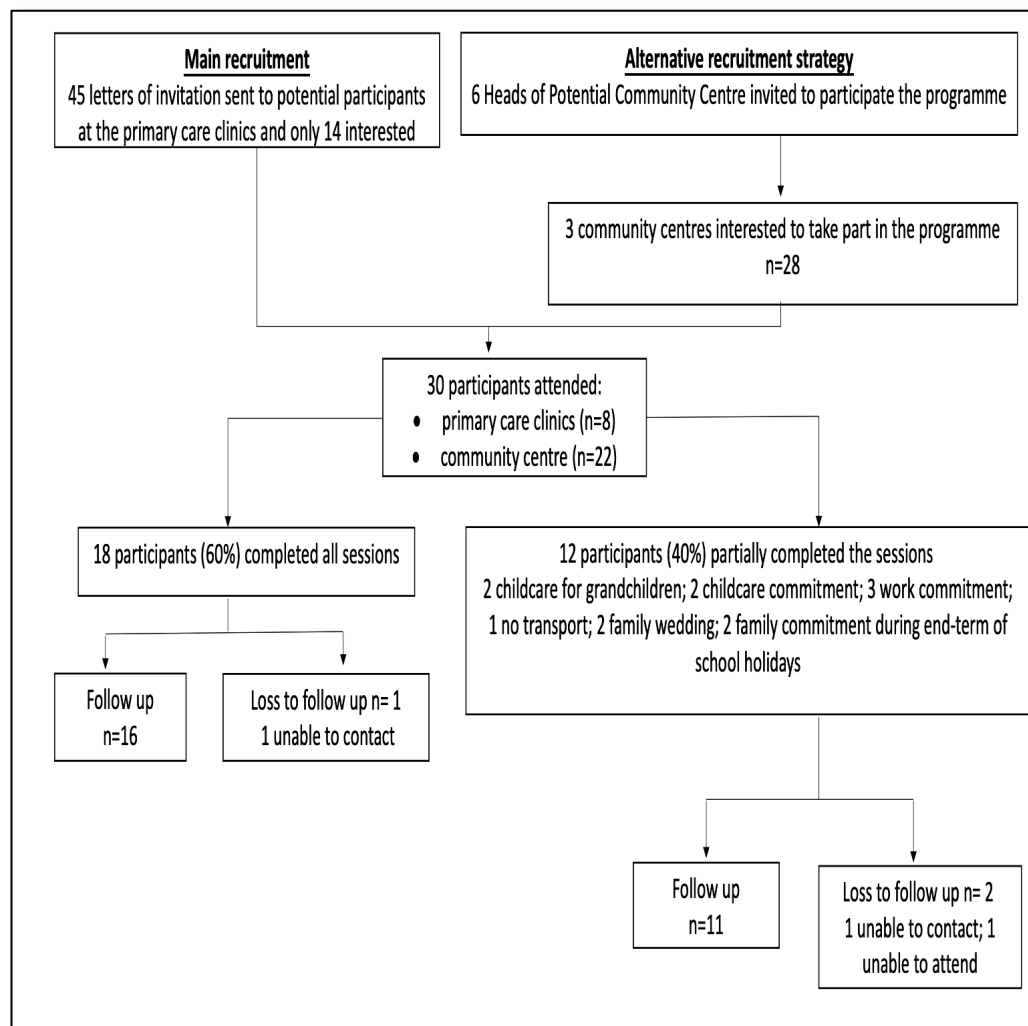
1. At least 20 participants recruited (30 participants were recruited).
2. Eleven sessions could be conducted (MY DEUMI group psychoeducational intervention has been successfully conducted for 5 groups; 4 groups completed 11 sessions, while 1 group completed 4 sessions).
3. Dropout rate was not higher than 30% (Dropout rates were at 30%).
4. Completion rate was at least 50% (60% of the participants completed all 11 sessions)
5. There were no major logistic issues that significantly affect the delivery of each session. (Low recruitment rate at the primary care clinics therefore, an alternative recruitment strategy was implemented).

The following paragraphs describe these results in more detail using process measure (Steckler and Linnan, 2002).

Recruitment and reach

Primary care clinics have been selected as the primary setting to recruit participants. Most people who are newly diagnosed with diabetes in Malaysia attend these clinics for their routine follow-up. Figure (53) displays MY DEUMI study flowchart.

Figure 53: MY DEUMI intervention flowchart.



Recruitment target for primary care clinics were not met, with a response rate of only 31% (n=45), and it was difficult to identify additional participants due to the limited time available (office hours only during weekdays), coupled with time constraints for the researcher (PhD timeframe limits the duration of data collection). Due to this low completion and response rate, the community centres were invited to participate, and this has yielded a better response rate (78%; n=28), where a total of 22 participants have given their consent and attended the MY DEUMI programme.

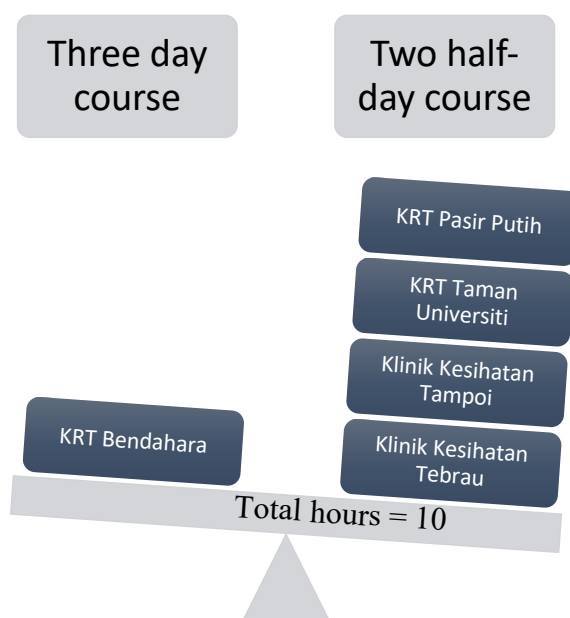
Overall, 30 participants have given their consent and attended the intervention programme. Of the 30, 18 participants (60%) completed all sessions, and 27 participants attended the follow-up session. Three participants failed to attend the follow-up (2 were uncontactable; 1 was unable to attend the follow up). Twelve participants (40%) partially completed the course for the following reasons: childcare for grandchildren (n=3); childcare commitment (n=2); work commitments (n=5); unavailability of transport (n=1); family wedding (n=2); and family commitments during term-end school holidays (n=2).

The primary analysis is presented based on the intention-to-treat (ITT) analysis (requiring all subjects to be analysed), while 3 participants failed to attend the follow-up, therefore, data imputation was performed to replace the missing data as recommended by (Dossing *et al.*, 2014). The missing data were brought in by a single imputation, through the adoption of the last-observation-carried-forward (LOCF) method. Apart from that, sensitivity analysis was also carried out on the data with and without imputation to ensure the robustness of the final results and the conclusion derived from the primary analysis (Thabane *et al.*, 2013).

Dose delivered and dose received

A total of five (5) groups participated and completed the introductory sessions. All sessions were organised according to participants' timing preferences. For 4 groups the sessions were conducted over two half-day on weekdays or weekends, while for the other group, it was conducted as a three-day course on weekdays. All groups received a total of 10 contact hours (see Figure 54).

Figure 54: List of the Primary Care Clinics and Community Centres (KRT), and the designated course of the MY DEUMI intervention.



The researcher conducted all the 11 sessions based on the manual except for one group from the community centre (KRT Pasir Putih), as they were unable to arrange a suitable time for one of the two half-day courses, due to activities during school holidays (family wedding, n=2; family commitments during end-term of school holidays, n=2; work commitment, n=1). Table (6.4) shows the intervention dose delivered and received by the participants for all groups.

Table 6.4: Dose delivered, and dose received in the MY DEUMI intervention.

Dose Delivered (Number of groups completed)	S1 (5)	S2 (5)	S3 (5)	S4 (5)	S5 (4)	S6 (4)	S7 (4)	S8 (4)	S9 (4)	S10 (4)	S11 (4)
Dose received venue 1 (two half-day course)	3	3	3	3	1	1	1	1	1	1	1
Dose received venue 2 (two half-day course)	5	5	5	5	4	4	4	4	4	4	4
Dose received venue 3 (two half-day course)	5	5	5	5	-	-	-	-	-	-	-
Dose received venue 4 (two half-day course)	7	7	7	7	4	4	4	4	4	4	4
Dose received venue 5 (3-day course)	10	10	10	10	5	5	5	9	5	9	9
Total dose (participants) received	30	30	30	30	14	14	14	18	18	18	18

Abbreviations: S=session; venue 1= Primary care clinic (Klinik Kesihatan Tebrau); venue 2=Primary care clinic (Klinik Kesihatan Tampoi); venue 3= community centre (KRT Pasir Putih); venue 4= community centre (KRT Taman Universiti); venue 5= community centre (KRT Bendahara)

Fidelity

The fidelity score assisted the researcher in monitoring the extent to which the intervention was conducted and delivered as outlined in the intervention manual. A mock session was conducted prior to the main study sessions to identify potential problems. The researcher used a self-report checklist (Appendix G) to ensure that all components were delivered.

Generally, all the sessions were conducted according to the intervention manual. However, in one of the groups, a slight logistic issue occurred, where some of participants were directed to the wrong seminar room at venue 2, causing the 1st session to be delayed for 40 minutes. It was successfully resolved because the group members agreed to stay on to complete the session. Table (6.5) illustrates the intervention components for each session and the fidelity score. Most of the intervention components were delivered as per the manual (Introduction1, Session 2, Session 5, Session 6, Session 7 and session 10). Nonetheless, activities for 6 sessions (40%) were shortened due to time constraints as a result of the sessions being conducted during weekdays at night or over the weekends.

Table 6.5: Summary of the fidelity assessment of the MY DEUMI intervention sessions.

Session	Intervention component	Session moderately delivered as written	Session delivered as written	Some activities were shortened	No activities were shortened
Introduction 1: Are you ready?	<ol style="list-style-type: none"> 1. Introduction to the whole programme: <ul style="list-style-type: none"> • Ground rules. • Programme approach. 2. Exploring participants hope. 		5/5		5/5
Introduction 2: Towards effective self-management	<ol style="list-style-type: none"> 1. Sharing moments: <ul style="list-style-type: none"> • Risk factors of T2DM • Individuals' ways to control sugar levels. 2. Eliciting change talk: <ul style="list-style-type: none"> • Benefits of lifestyle change. 3. Individual assessment: <ul style="list-style-type: none"> • Diabetes knowledge quiz. 		5/5	1/5	4/5
Session 1: What is diabetes?	<ol style="list-style-type: none"> 1. Exploring the understanding of the disease process: <ul style="list-style-type: none"> • Feedback from the visual aid (Poster Malaysians at risk!). • Matching the boxes to the labels (Normal food digestion process). • Group discussion regarding insulin regulation. • Completion of a diagram for complications that they might face or already experienced. 2. Eliciting change talk: <ul style="list-style-type: none"> • Reason to reduce the complications. 		5/5		5/5

Session	Intervention component	Session moderately delivered as written	Session delivered as written	Some activities were shortened	No activities were shortened
	3. Goal setting: <ul style="list-style-type: none"> • Effective goal setting techniques. • Discussion in pairs and writing of personal goal. 				
Session 2: A sweet through time	1. Exploring views: <ul style="list-style-type: none"> • Reflection of visual aid (figure of adults who died from diabetes, human immunodeficiency virus (HIV)/ Acquired immune deficiency syndrome (AIDS), tuberculosis and malaria). • Reflection of figures on how risks of complications can be reduced with a reduction of HbA1c (% or mmol/mol). • Discussion regarding recommended type of food or drinks. 2. Low glycaemic index diet quiz. 3. Method to reduce carbohydrate intake 4. Exploring perspectives: <ul style="list-style-type: none"> • Activity called “good and not so good things” (what is good and not so good consuming too much rice?) 5. Exploring barriers in healthy eating and ways to overcome them. 6. Goal setting: discussion in pairs		5/5	2/5	3/5

Session	Intervention component	Session moderately delivered as written	Session delivered as written	Some activities were shortened	No activities were shortened
Session 3: Diabetes medicine guide	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> Myth or fact about insulin Sharing moments of prescribed medicine and how the medicine works Offer information regarding insulin action Exploring fears of insulin through a discussion of its beneficial value. Reflection: the importance of this session. 		5/5		5/5
Session 4: Keep calm and let's play	<p>Activity 1 (Food labels)</p> <ul style="list-style-type: none"> Recommended amount of carbohydrate, fat and salt per day. How to read food labels (handout) Reading labels on the displayed food packages. <p>Activity 2 (Sugar game)</p> <ul style="list-style-type: none"> Calculate the number of teaspoons of sugar contained in local food products, which are mainly consumed by Malaysians. Reflections on the amount of sugar in each drink and food. <p>Activity 3 (review pedometer).</p> <ul style="list-style-type: none"> How to use a pedometer. 		5/5		5/5

Session	Intervention component	Session moderately delivered as written	Session delivered as written	Some activities were shortened	No activities were shortened
Session 5: Let's move! To stay healthy and lose weight	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> Sharing moments of successful weight loss experience. Recommendation for physical activity. Eliciting change talk: <ul style="list-style-type: none"> Reason of walking as a form of exercise. Exploring barriers and ways to increase physical activity. 		4/4	2/4	2/4
Session 6: Keep calm and keep walking!	<ol style="list-style-type: none"> Exploring view through reflections on visual aid (activities that burn calories). Broadening perspectives: My typical day and opportunity to increase the number of steps. Into action: tools and type of activity. Activity: walking around the seminar room and measuring the total calories used. Goal setting: Individual target (number of steps a day). 		4/4	1/4	3/4
Session 7: Diabetes foot	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> Reflection on visual aid (diabetic foot ulcer) and ways to reduce the risk Activity 1: Risk assessment (diabetes foot ulcer risk assessment questionnaire) Activity 2: Step-by-step daily foot care. 		4/4	1/4	3/4

Session	Intervention component	Session moderately delivered as written	Session delivered as written	Some activities were shortened	No activities were shortened
Session 8: Dealing with diabetes	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> Individual activity: Feeling identification. Group activity: The importance of stress management. Activity and reflection 1: Motivational game named 'Come on Six by Tom Jackson's) Activity and reflection 2: Stress level measurement and ways to reduce anxiety or stress. Activity 3: Deep breathing technique. 		4/4		4/4
Session 9: Complementary and alternative medicine (CAM)-Herbal medicine	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> To assess the number of participants interested in using CAM (herbal medicine). Group discussion: How CAM helps in diabetes management. Activity 1: Discussion in pairs on the effectiveness of herbal medicine. Providing information: List of herbs used for T2DM (How they work and the potential side effects). Reflection of the whole session. 		4/4		4/4

Session	Intervention component	Session moderately delivered as written	Session delivered as written	Some activities were shortened	No activities were shortened
Session 10: Relapse prevention	<ol style="list-style-type: none"> 1. Broadening perspectives: Case study 2. Activity 1: Discussion in pairs on how lapse changes to relapse. 3. Activity 2: Inspiration and motivation (success stories from group members or someone outside the group) 4. Activity 3: Confidence ruler and ways to increase confidence. 5. Reflection of the whole session 		4/4	2/4	2/4
Session 11: Closing	<ol style="list-style-type: none"> 1. Exploring view: What they have gained throughout the programme. 2. Evaluation: Discussion in pairs of the most enjoyable and helpful activity. 3. Summary and closing: reminder of telephone follow-up and 12-week review of glycaemic control. 		4/4		4/4

6.5.3 Descriptive statistics

Descriptive statistics (means (M), standard deviation (SD) and median, as well the interquartile range (IQR) were computed to describe the outcome measure (see Table 4). Generally, the fasting plasma glucose level among the MY DEUMI participants appeared to improve (levels lower) following the intervention, $M=7.82$, $SD=1.57$, 95% CI [7.23, 8.41] as compared to before the intervention, $M=9.36$, $SD=2.52$, 95% CI [8.42, 10.31]. The inferential test will be discussed in the next section.

6.5.4 Preliminary effect of outcome measure

Main outcomes: The Fasting plasma glucose (FPG) (mmol/L) and the Body mass index (BMI) (kg/m^2).

A paired-samples t-test was used to determine whether there was a statistically significant mean difference in the fasting blood glucose level 12 weeks after the intervention (see Table 6.6). The assumption of normality was not violated, as assessed by the Shapiro-Wilk's test ($p=0.233$), where there was a statistically significant mean reduction in participants' fasting blood glucose level after receiving 10 hours of the MY DEUMI intervention (mean reduction 1.54, 95% CI, 0.67 to 2.42 mmol/L, $t(29)=3.618$, $p < 0.001$).

Meanwhile, the assumptions for normality were not met for the BMI as assessed by the Shapiro-Wilk's test ($p < 0.001$), therefore, the Wilcoxon-signed rank test was used, and it was found that the median rank of weight (kg) post-intervention, median =67.2, IQR=18, was statistically significantly lower than the median rank of weight (kg) at pre-intervention, median=69.0, IQR=20 ($Z=2.19$, $p < 0.05$).

Whereas, the BMI score demonstrated that there was a significant difference ($Z=2.64$, $p < 0.01$) between the BMI after the MY DEUMI intervention compared to the BMI before the intervention. The median score after the intervention was 25.7 (IQR=7.1), compared to 26.4 (IQR=7.9) before the intervention. Table 6 provides a summary of the preliminary outcomes of the MY DEUMI intervention for the FPG (mmol/L), weight (kg) and BMI (kg/m²).

Table 6.6: Baseline differences in mean and median including the statistical test for the fasting plasma glucose (FPG), weight and the body mass index (BMI) outcome.

Paired t-test					
	Pre-Mean (SD) N=30	Post-Mean (SD) N=30	t	df	p
FPG (mmol/L)	9.36 (2.52)	7.82 (1.57)	3.618	29	0.0001***
Wilcoxon signed rank test					
	Pre-median (IQR) N=30	Post-median (IQR) N=30		z	p
Weight (kg)	69.0 (20)	67.2 (18)		-2.19	0.029*
BMI (kg/m ²)	26.4 (7.9)	25.7 (7.1)		-2.64	0.008**
Abbreviations: FPG= Fasting plasma glucose, BMI= Body mass index, IQR= Interquartile range, * significant at p < 0.05, ** significant at p < 0.01, *** significant at p < 0.001					

Secondary outcomes: Diabetes self-management practice (DSMQ) and self-efficacy in diabetes management (DMSES).

In order to obtain the preliminary estimate of the improvement in the secondary outcome measure of diabetes self-management practice among the MY DEUMI intervention participants, the Wilcoxon signed rank test was conducted. The overall effect of diabetes self-management practice (DSMQ) was significant for all sub-domain measure: blood glucose management, median difference=2.25, $Z=4.528$, $p <$

0.001; diet management, median difference=0.62, $Z=3.568$, $p<0.01$; physical activity management, median difference= 1.67, $Z=4.012$, $p <0.001$; healthcare use, median difference=2.08, $Z=4.509$, $p< 0.001$; Total score of DSMQ, median difference= 1.34, $Z=4.543$, $p < 0.001$.

Apart from that, the Wilcoxon signed rank test was also conducted to evaluate whether participants' self-efficacy indicates an improved diabetes self-management. The result indicated a significant difference, where $Z= 4.43$, $p< 0.001$ while the median difference was 23.5. Table (6.7) shows a summary of the inferential test analysis for self-management practice (DSMQ) and self-efficacy in diabetes management (DMSES UK) among the MY DEUMI participants.

Table 6.7: The Wilcoxon signed rank test results for self-reporting diabetes self-management practice (DSMQ) and self-efficacy in diabetes management (DMSES UK) among the MY DEUMI participants.

	Wilcoxon signed rank test			
	Pre-median (IQR)	Post-median (IQR)	<i>z</i>	<i>p</i>
Self-management practice (DSMQ):				
• Glucose management	6.50 (0.25)	8.75 (2.0)	-4.528	0.001***
• Diet management	6.88 (1.25)	7.50 (0.63)	-3.568	0.018**
• Physical activity management	5.83(0.83)	7.50 (0.83)	-4.012	0.001***
• Healthcare use	6.25 (0.83)	8.33 (1.25)	-4.509	0.001***
• Total self-management practice	6.47 (0.47)	7.81 (0.97)	-4.543	0.001***
Self-Efficacy for T2DM self-management (DMSES UK)	137.50 (11.50)	160.00(8.50)	-4.434	0.001***
Abbreviations: Diabetes Self-Management Questionnaire (DSMQ), Diabetes Management Self-Efficacy Scale United Kingdom (DMSES UK), IQR= Interquartile range, * significant at $p < 0.05$, ** significant at $p < 0.01$, *** significant at $p < 0.001$				

6.5.5 Effect sizes

The paired t-test and the Wilcoxon signed rank test suggested that there are improvements in glycaemic control, self-efficacy in diabetes management and diabetes self-management 12 weeks after the participants completed the MY DEUMI intervention. There was a moderate effect of the MY DEUMI intervention on improved fasting plasma glucose level (see Table 6.8). However, there were small effects for weight (kg) and BMI (kg/m²) improvement among the participants.

Meanwhile, the effect size for self-efficacy in diabetes management (DMSES UK) and self-management practice (DSMQ) were generally large, and there was a moderate effect for improved (sub-domain) dietary management for DSMQ (see Table 6.8).

Table 6.8: Cohen's d and r effect size for primary and secondary outcome measures.

Measures	Cohen's d (effect size)	r (effect size)
FPG (mmol/L)	0.65	
Weight (kg)		0.28
Body Mass Index (kg/m ²)		0.34
Self-management practice (DSMQ):		
• Glycaemic control		0.58
• Dietary control		0.31
• Physical activity		0.53
• Healthcare use		0.61
• Sum score of DSMQ		0.60
Self-Efficacy for T2DM self-management (DMSES UK)		0.57

6.5.6 Acceptability of MY DEUMI

6.5.6.1 User experiences (Process evaluation questionnaire feedback)

Most participants positively rated all the domains on the evaluation form: facilitator; topic; materials; time management; and objective. Although the scale ranges between 5 (Excellent), 4 (Good), 3 (Moderate), 2 (Fair) and 1 (poor), it is unlikely to find an output lower than three (3). Table (6.9) summarises the response from the participants.

Table 6.9: Summary of the process evaluation questionnaire response.

Domain		Level of quality (5-point Likert scale) N=27		
		Excellent n (%)	Good n (%)	Moderate n (%)
Facilitator	Knowledgeable	15 (56)	12 (44)	
	Clear and concise	20 (74)	7 (26)	
	Time management	9 (33)	18 (67)	
	Two-way communication	11 (41)	6 (22)	
Topic	Important and relevant	20 (74)	7 (26)	
Materials	Quality	20 (74)	5 (19)	2 (7)
	Easy to understand	20 (74)	7 (26)	
Time management	Question and answer session	9 (33)	16 (59)	2 (7)
	Hands-on session	11 (41)	16 (59)	
	Evaluation	15 (56)	9 (33)	3 (11)
Objective	Explained	10 (37)	17 (63)	
	Achieved	16 (59)	11 (41)	
		Extremely likely n (%)	Likely n (%)	Neutral n (%)
Output	I will do changes in future	15 (56)	10 (37)	2 (7)
	I will use the provided materials	12 (44)	12 (44)	3 (12)
	I will look for extra information	19 (71)	6 (22)	2 (7)

Most participants reported that the facilitator delivered the programme clearly and concisely (74%), with good two-way communication (41%). They agreed that all the topics presented were important and relevant. They were satisfied that the quality of the material was comprehensible, 74% scored it as excellent. Around 60% of the participants reflected that the objectives of the programme were achieved. However, less than 50% of the participants rated time management as excellent (question and answer sessions and hands-on session), and therefore this seems to be an area that needs improvement. Figure (55) illustrates the overall feedback from the MY DEUMI participants.

In addition to the usual domains, the researcher has included another section on the evaluation form concerning the output or participants' behavioural intentions, and 71% of the participants reported they were very likely to search for additional information regarding T2DM, and 56% claimed they would make some changes in future (see Figure 56). In a nutshell, most participants were happy and satisfied with the delivery of the MY DEUMI intervention.

Figure 55: The overall feedback by the MY DEUMI participants on the MY DEUMI intervention.

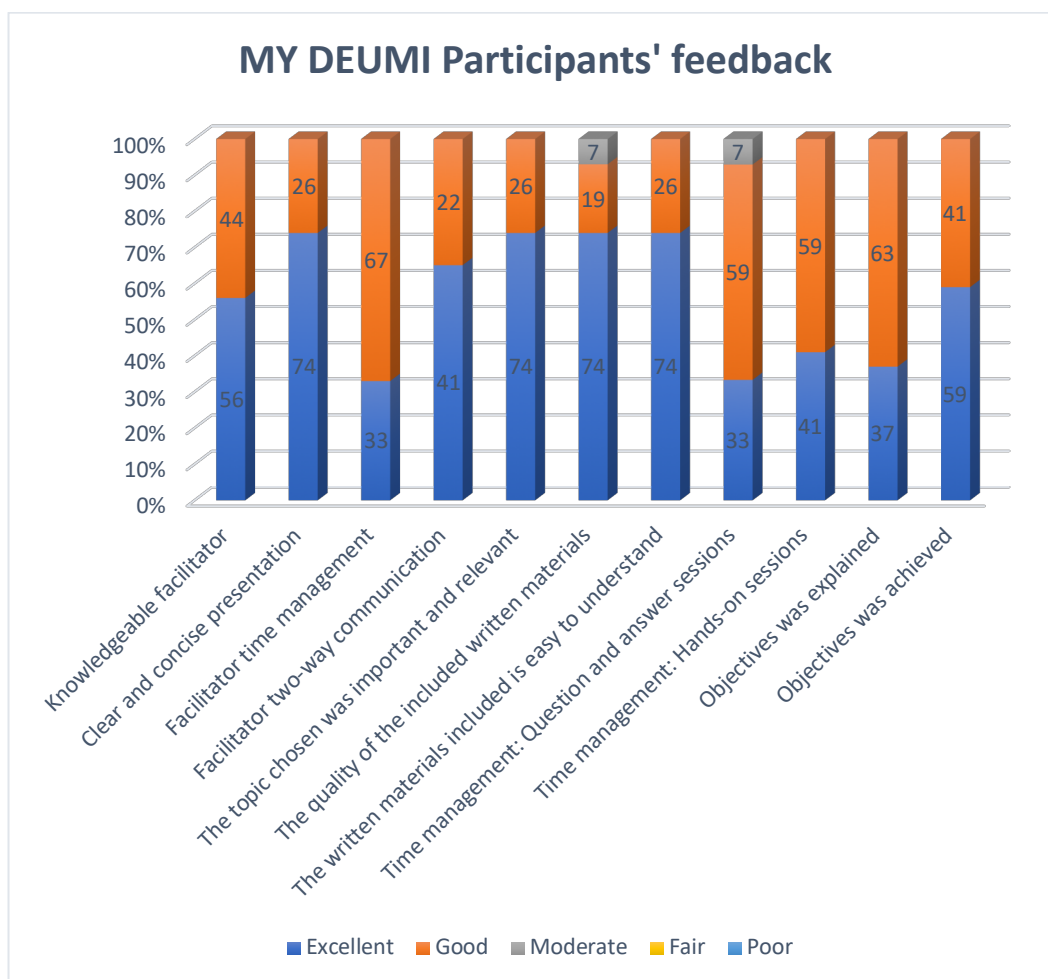
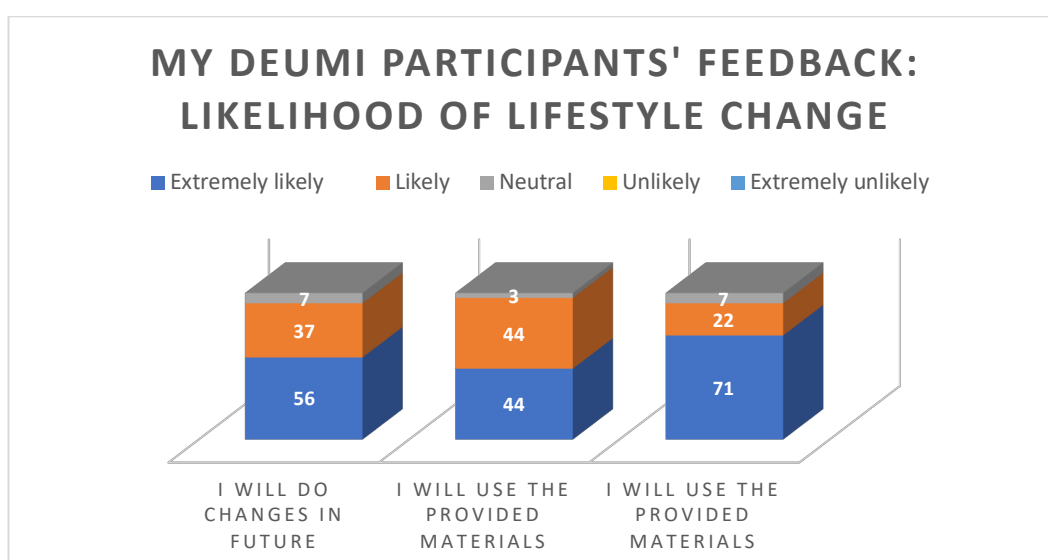
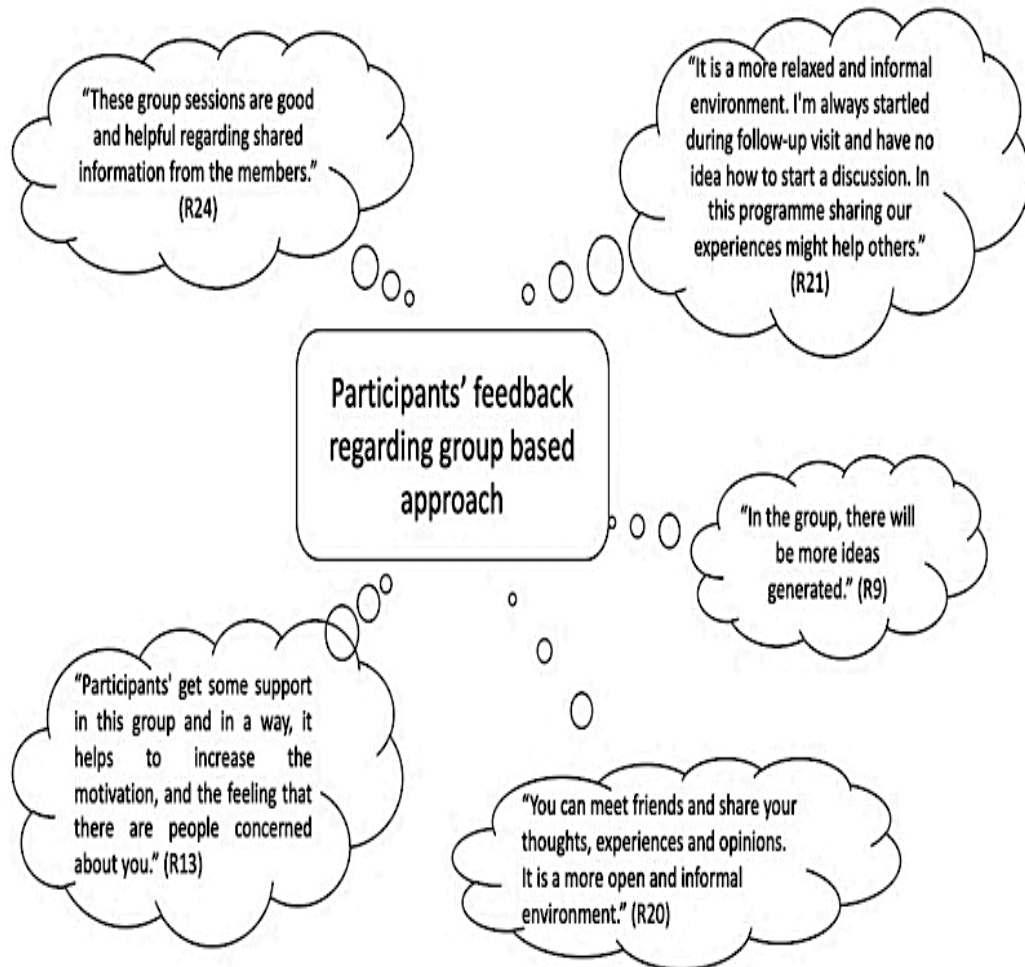


Figure 56: The MY DEUMI participants' feedback regarding the likelihood of lifestyle change post-intervention.



Participants also highlighted the benefits gained through the group-based approach. Figure (57) shows some quotes from the feedback corresponding to group delivery of the MY DEUMI intervention.

Figure 57: Examples quotes expressed by participants regarding benefits gained through the group-based approach.



6.5.6.2 A qualitative process evaluation (Exit interviews)

Open ended semi-structured interviews were also conducted to determine the acceptability of the MY DEUMI intervention. All participants were invited to be interviewed at their convenience after their follow-up session. Ten participants were willing and available to be interviewed. Table (6.10) describes their sociodemographic characteristics and compares them with those who did not participate in the interviews. Interviews were conducted at a convenient location for the participants, mainly at their home (n=8).

Table 6.10: Comparison of sociodemographic characteristics of the MY DEUMI participants who participated (n=10) and did not participate in the exit interviews (n=20).

		Participants who participated in the exit interview (n=10)		Participants who did not participate in the exit interview (n=20)		<i>p</i> value
		Mean (SD)	N (%)	Mean (SD)	N (%)	
Age in years (Range)		56 (10.9) (46-68)		56 (9.2) (35-72)		0.001
Gender	Male		1 (10)		6 (30)	0.372
	Female		9 (90)		14(70)	
Status of employment	Employed		2 (20)		13(65)	0.066
	Housewife		6 (60)		5(25)	
	Retiree		2 (20)		2(10)	
Duration of diagnosis (month)	< 12 months		2 (20)		3(15)	0.001
	≥ 12 months		2 (20)		4(20)	
	≥ 24 months		1 (10)		3(15)	
	≥ 36 months		1 (10)		4(20)	
	≥ 48 months		1 (10)		1 (5)	
Complementary medicine user	Herbal medicine		3 (30)		5(25)	0.015
			7 (70)		4 (20)	

Two initial themes were identified from the exit interviews and illustrated in Figure (58) as listed below:

- i. Benefits of the MY DEUMI intervention for physical health, social functioning and well-being.
- ii. Barriers to engaging in the MY DEUMI intervention: health beliefs and personal commitments.

The following Figure (59) displays the percentage of participants' feedback corresponding to each theme. Meanwhile, Tables (6.11, 6.12, 6.13 and 6.14 display some quotes from the participants to further strengthen their feedback.

Figure 58: The MY DEUMI participants experiences, outcome and feedback.

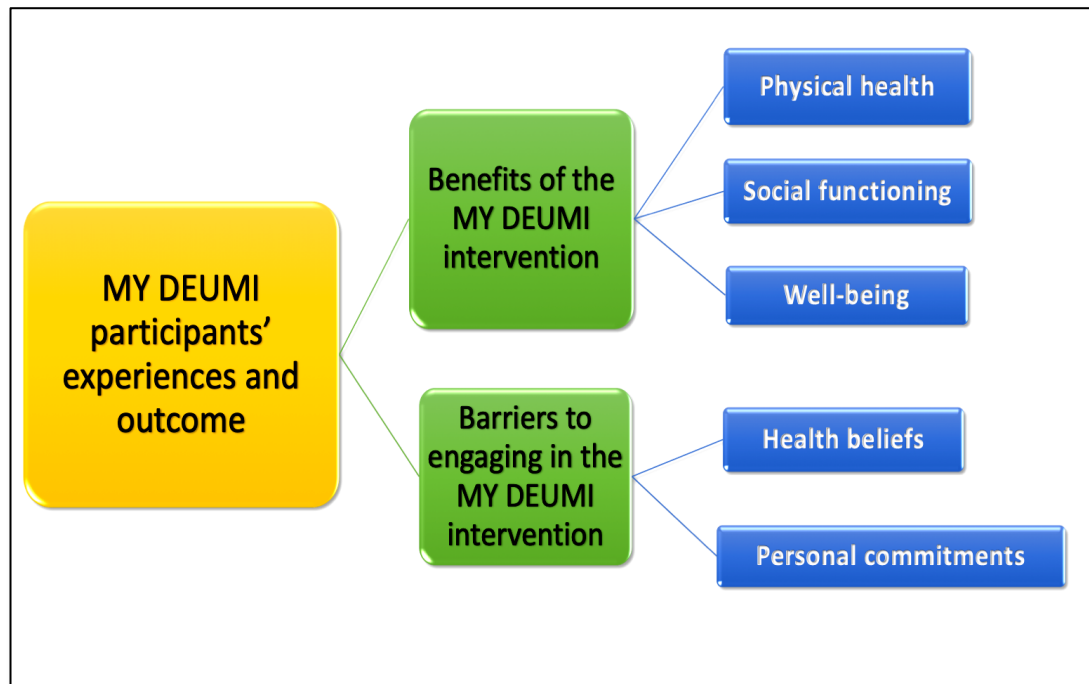
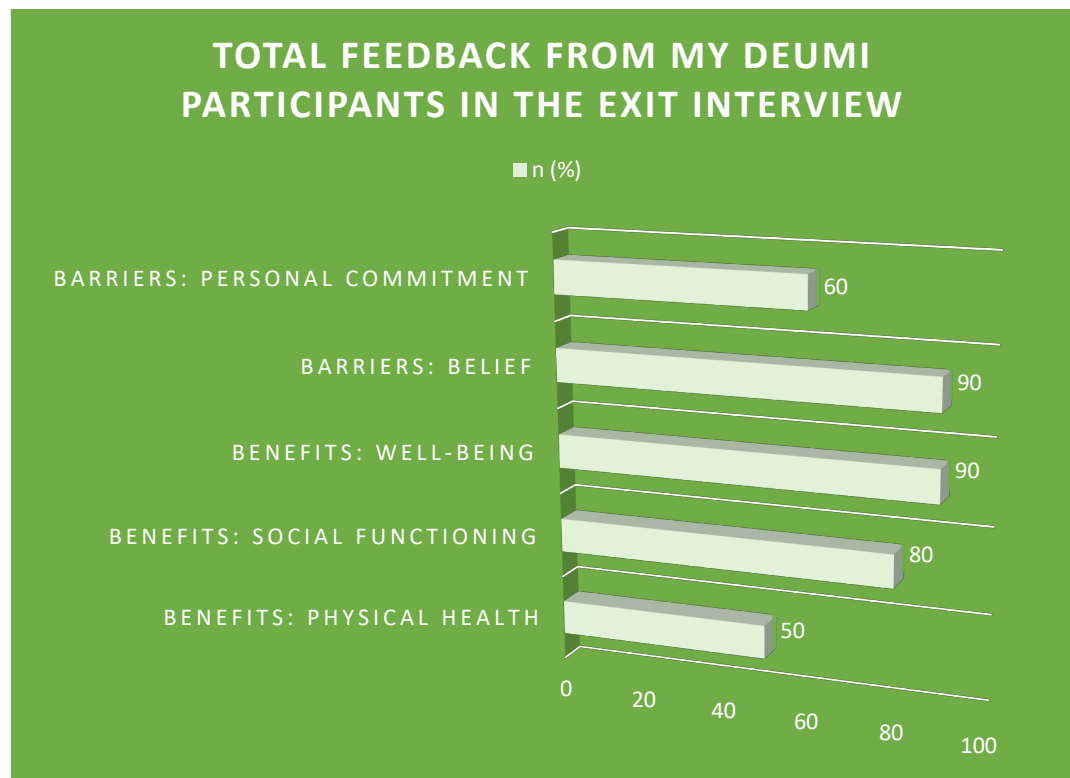


Figure 59: Feedback from the MY DEUMI participants during the exit interviews (N=10).



At least half of the participants who attended the exit interviews claimed that they feel improvement in terms of health and physically. Table (6.11) presents the samples of quotes shared by the participants.

Table 6.11: Physical effect theme and examples of quotes.

Main theme	Sub-theme	Excerpts	N (%)
Benefits of the MY DEUMI intervention	Physical health	<p><i>“I’ve lost about 3 kg following the prescribed diet. Now, I feel much easier for me to rise from a sitting position. I’m taking part in the 10 000 steps activity twice weekly around the housing area organised by the ladies’ society.”</i> (R9, female, housewife, aged 45).</p> <p><i>“I feel better than before, and my blood sugar (glucose) level is getting controlled. I reckon this is due to the action that I have taken from the information given such as having adequate sleep and a good stress management.”</i> (R13, male, employed, aged 60).</p> <p><i>“I managed to lose some weight, and sugar reading is getting better.”</i> (R21, female, housewife, aged 57).</p> <p><i>“Now, my hand numbness is lessening.”</i> (R24, female, housewife, aged 44).</p>	5 (50)

Another sub-theme benefit of the MY DEUMI experienced by the participants was in social functioning. A majority of the participants agreed that the delivery method was interesting, interactive and effective to assist them in their diabetes self-management, and to enjoy doing it with family and friends (see Table 6.12). In addition, the materials included were helpful and worked as post-intervention reference when they were managing their diabetes themselves.

Table 6.12: Benefits theme and sub-themes, as well the sample quotes from the exit interviews.

Main theme	Sub-theme	Excerpts	N (%)
Benefits of the MY DEUMI intervention	Social functioning	<p><i>“Thank God, I’ve received much support from my husband after reading all the materials given. The label reader is very helpful for my shopping activity.”</i> (R9, female, housewife, aged 45).</p> <p><i>“As I mentioned earlier the brochure and diary are very helpful. The information delivered can be referred to and helps me to maintain momentum in my health care.”</i> (R13, male, employed, aged 60).</p> <p><i>“I have joined the aerobic team to improve my blood circulation and found that it is a fun activity that I can do with friends, rather than watching TV from morning till evening, while at the same time helps me to deviate from my worries. I’ve changed my diet from chocolate drink to oats and take only one sweet drink a day.”</i> (R24, female, housewife, aged 44).</p> <p><i>“Peoples’ experiences and the discussion sessions have opened my mind.”</i> (R8, female, retiree, aged 70).</p> <p><i>“It was straightforward and easy to understand. We are more open to the group to discuss specific issues, or any misunderstanding while strengthening our bond (among the KRT members).”</i> (R19, female, housewife, aged 43).</p>	8 (80)

The majority of the participants shared their improvement in well-being, such as having an improved self-control and reduced anxiety (see Table 6.13). This improvement benefited them in terms of lifestyle change, while optimising their diabetes self-management.

Table 6.13: Well-being theme and sub-themes with samples of quotes from the exit interviews.

Main theme	Sub-theme	Excerpts	N (%)
Benefits of the MY DEUMI intervention	Well-being	<p><i>“I’m more aware of my food choices and do not eat indiscriminately.” (R16, female, employed, aged 46).</i></p> <p><i>“My uncontrolled sugar (glucose) level before was due to irregular medication intake, and the most important thing is diet control. Thank God, I’ve changed, and it makes a difference.” (R21, female, housewife, aged 57).</i></p> <p><i>“I’m more conscious of our meal times and keeping it on schedule, and my husband managed to cut down his portions, which is good for him.” (R27, female, housewife, aged 44).</i></p> <p><i>“I am calmer after the programme. The exposure regarding the importance of sharing problems to get support, helps to improve my emotions and health.” (R13, male, employed, aged 60).</i></p> <p><i>“I feel relieved and less worried than before.” (R16)</i></p> <p><i>“Looking at my health now, I’m getting more confident, cheerful, calmer and not as disappointed in myself because of the uncontrolled blood sugar level.” (R21, female, housewife, aged 57)</i></p>	9 (90)

However, most participants claimed that there were some barriers to engaging in education activities among Malaysians, such as belief and personal commitment. Some participants have a bad impression regarding diabetes education as they may experience less effective session previously, but some highlighted the importance of personal belief regarding diabetes education. Table (6.14) illustrates some of the sample quotes shared by the participants during the exit interviews, regarding the potential barriers in delivering diabetes education to the community.

Table 6.14: Barriers theme and sub-themes as well the sample of quotes from the exit interviews.

Main theme	Sub-theme	Excerpts	N (%)
Barriers to engaging in the MY DEUMI intervention	Health Beliefs	<p><i>“After receiving the invitation, I was 50-50 about joining because I felt like it was going to waste my time.” (R13)</i></p> <p><i>“People usually come to primary care clinic for an appointment, and they don’t expect to join any other programmes.” (R16, female, employed, aged 46).</i></p> <p><i>“This is all about self-willingness. We will spare our time for such programme unless if there is an inevitable reason or family commitment.” (R19, female, housewife, aged 43).</i></p> <p><i>“Some of my friends don’t take health matter seriously but for me, health is everything. Therefore, I’m here to listen and learn more. They will always have excuses to not attend any good health programmes.” (R24, female, housewife, aged 44).</i></p>	9 (90)

	Personal commitment	<p><i>“At this time of the year wedding invitations are mostly likely to be a barrier. My schedule is always packed.”</i> (R9, female, housewife, aged 45).</p> <p><i>“Sometimes there's family visiting. Couldn't attend the course to stay with the guests or other commitments such as a wedding or feast invitations.”</i> (R19, female, housewife, aged 43).</p> <p><i>“Babysitting my grandkids is the main reason I missed one of the sessions.”</i> (R13, male, employed, aged 60).</p>	6 (60)
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In addition, there were also opinions relating to the location of where the MY DEUMI intervention was delivered (primary care clinics and community centres) (see table 6.15).

Table 6.15: Quotes from the participants with differing opinions regarding the venue of the intervention.

Primary care clinic	Community centre
<p><i>“This programme is brilliant because doctors do not have the time (high number of patients) to go into more details about diseases. However, they will find the time to talk to us too but not as detailed as in this programme.”</i> (R8, female, retiree, aged 70).</p>	<p><i>“A proverb says ‘Killing two birds with one stone’. We managed to combine this kind of activity with our routine weekly meeting at the community centre. We know each other and there is no need for an ice-breaker, and participants feel comfortable and are open for discussion.”</i> (R16, female, employed, aged 46).</p>

<p><i>“We are afraid to take up so much of the nurses’ and doctors’ time in the busy clinic, asking more about our disease. Another reason is we only go to the clinic to get a consultation and medicine.”</i> (R21, female, housewife, aged 57).</p> <p><i>“It is not suitable in the clinic because of the busy environment (high number of patients). If the doctors deliver this kind of programme, they need to sacrifice their working time, which is much needed for follow up patients. Another issue is the anxious feeling while getting the blood results prior to a follow-up consultation, making people feel they are not ready for any education session.”</i> (R17, female, retiree, aged 63).</p>	<p><i>“If it is conducted in the community centre, we will always be in a group, it is less formal (open for discussion) and more fun.”</i> (R19, female, housewife, aged 43).</p> <p><i>“The reason for this is we live in the same community or area, we are neighbours, and the distance help us to exchange more information and experiences.”</i> (R21, female, housewife, aged 57).</p> <p><i>“If I can’t attend any of the sessions, I’m still able to gain information from my colleagues within the community centre.”</i> (R24, female, housewife, aged 44).</p>
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Figure 60: Snapshots of the hands-on activities and example of the reflection sessions in the MY DEUMI intervention.



6.6 Discussion

The results of this small feasibility study to investigate the acceptability of group diabetes education enhanced motivational interviewing (MY DEUMI) intervention have shown that the participants found the intervention practical and acceptable, and the outcome measure indicated that there was some improvement in glycaemic control for Malaysians with T2DM. The discussion section is divided into three sub-sections related to the study aims.

6.6.1 Feasibility of MY DEUMI

The rate of participation, attendance and completion rate are the indicators used for assessing the feasibility of educational interventions. The recruitment rate at the primary care clinic was low (31%, n=45), when compared with a RCT of individual diabetes education intervention (78%, n=164) among Malaysian adults with diabetes (Tan *et al.*, 2011). The low turnout among participants in the primary care clinic occurred mainly due to the timing of the course (work commitments or childcare for grandchildren).

The main role of the primary care clinic is to provide follow-up care for people with T2DM, however, engaging and recruiting participants have proven to be difficult. Previous quantitative surveys among general practitioners (GP) in Germany have suggested that timing (during clinic hours) and hectic work schedules in the clinics are the main barriers for GPs to refer their patients for research recruitment in a primary care setting (Hummerts-pradier *et al.*, 2008). In addition, a recent qualitative study reported that unsuitable timing because of other personal commitments is one of the reasons people with T2DM have not attended group diabetes education programmes in the UK (Winkley *et al.*, 2015).

To offset the problems recruiting from primary care clinics the researcher was able to recruit participants at community centres, which is mainly due to the flexible hours offered (during weekends or evenings), and the flexibility in arranging the day and time for group members to attend the intervention. Text messages and phone call reminders, as well as incentives may be considered to increase participation rate, as suggested in a systematic review of experimental studies, investigating the methods used to increase the response rate in survey research (Vangeest, Johnson and Welch, 2007). Therefore, healthcare professionals should consider conducting diabetes educational programmes at suitable times or extended times (after office hours or over weekend) to maximise uptake.

Meanwhile, in the current study the process evaluation demonstrated that the MY DEUMI intervention is feasible for people with T2DM. Sixty percent of the participants completed all the 11 MY DEUMI sessions, and around 46% completed at least 7 sessions. Although the sample size was small, the intervention has a high completion rate, and all the participants attended and completed the first 4 sessions. Moreover, considering the total hours (10 hours) of the intervention with 11 sessions it requires a great deal of commitment from the participants, and therefore it is believed that the intervention is feasible and beneficial for the participants.

6.6.2 Preliminary results of outcome measure

At 12 weeks follow-up post-MY DEUMI intervention, there was a statistically significant improvement in: fasting plasma glucose (mmol/L); BMI (kg/m²); self-efficacy measured with the Diabetes Management Self-Efficacy Scale United Kingdom (DMSES UK); and the diabetes self-management practice was measured using the Diabetes Self-Management Questionnaire (DSMQ). For all outcomes there was a statistically significant improvement: FPG, mean reduction 1.54, 95% CI, 0.67 to 2.42 mmol/L, $t(29) = 3.618$, $p < 0.001$, $d = 0.65$; BMI, median difference 0.7, $Z = 2.64$, $p < 0.01$, $r = 0.34$; self-efficacy, median difference 1.34, $Z = 4.543$, $p < 0.001$, $r = 0.57$; and self-management practice, median difference = 1.34, $Z = 4.543$, $p < 0.001$, $r = 0.6$ with small to moderate effect size.

These positive results are supported by a previous systematic review and meta-analysis of 13 RCTs (N=3128) where diabetes education was enhanced with a motivational approach for people with type 1 and type 2 diabetes. This demonstrated that motivational interventions improve diabetes self-management, and are associated with a 0.17% (95% CI, [-0.09%, 0.43%]) reduction in HbA1c among participants in the intervention groups, compared to the control group (Jones *et al.*, 2014). However, the outcome was not statistically significant due to the small number of studies included and issues of heterogeneity. Therefore, more research is recommended and to include outcome measures of behaviour change.

Participants in receipt of the MY DEUMI intervention have reported improved self-efficacy and diabetes self-management. These findings suggest that group psycho-education for people with T2DM is potentially effective, and may promote uptake of this type of approach in Malaysia. According to (Sudhir, 2017), who reviewed and examined the literature in India on psychoeducational interventions

between 2015 and 2017 for people diagnosed with lifestyle disorder (type 2 diabetes and cardiovascular disease), which demonstrated an improvement in the physiological outcome, self-efficacy and sense of empowerment. Moreover, the review also highlighted the importance of utilizing advanced information technology, such as internet based and mobile phone applications in psychoeducation interventions, in order to reach more people and to support their daily diabetes self-management. Similarly, results of this study are supported by a systematic review of 10 RCTs aimed to determine the effectiveness of diabetes self-management education using motivational interviewing techniques, and it was concluded that this approach has proven to be effective in improving diabetes self-management in the short term (<6-months) (Song, Xu and Sun, 2014).

Despite the positive changes in the outcome measures for the MY DEUMI intervention the results should be interpreted cautiously due to the small sample size, short-term follow up period and the lack of a control group. The overall effect may be smaller if the study is repeated as a full-scale randomised controlled trial (Craig *et al.*, 2008). To conclude, the MY DEUMI intervention provides clear information for people with diabetes, and practical techniques for diabetes self-management, which may help them to improve their health outcomes.

6.6.3 Acceptability of MY DEUMI

Overall, the MY DEUMI intervention is acceptable for participants and the majority of the participants have given positive feedback about the programme. Responses from the evaluation questionnaire completed at the end of the intervention, or at the time of follow-up, and the exit interviews suggested that they found the MY DEUMI intervention helpful, beneficial and easy to understand. They valued the interactive delivery style of the programme, and most participants claimed that they would search for more information regarding diabetes, and most felt confident that they can change their lifestyle in future.

Further exploration of participants' evaluation of this feasibility study was made during the exit interviews. Most of the participants interviewed claimed that they were able to optimise lifestyle changes, were in control of their diabetes self-management, and had good glycaemic control. This feedback is supported by previous research, which suggested that group-based education involving patient empowerment is associated with improved glycaemic control and patient well-being (Deakin *et al.*, 2006; Davies *et al.*, 2008; Inzucchi *et al.*, 2012).

The qualitative exit interviews produced insightful and valuable data, from which numerous conclusions can be drawn. The majority of the participants claimed they were satisfied with the programme, and have given positive feedback regarding the group-based approach and the motivational interviewing technique used. Patients' satisfaction is an important factor that can increase the likelihood of future lifestyle changes, and optimum diabetes self-management, as revealed in an RCT named PRIDE (Partner to Improve Diabetes Education), which is a study among low income people with T2DM (N=411) in Tennessee, USA, investigating the association between

effective health communication and metabolic control. It demonstrated that positive experiences and good health communication (patient and health professionals) increased patient satisfaction, as well as improve glycaemic control and medication adherence in the intervention group (White *et al.*, 2015).

However, despite all the improvement, some participants highlighted the issue of the low attendance at the primary care clinic. They claimed that the primary care centre is only for clinical consultations, and their daily routine commitments have made it impossible for them to join any educational programmes. Apart from that, the busy and bustling environment (walk-in system where there are lots of patients at all times) in most of the primary care clinics have resulted in unconducive conditions for education sessions, even though education sessions are generally conducted in the seminar room. This is supported by a study in South Africa, claiming health centres (primary care clinics) are not suitable for education, due to the unsupportive conditions, such as hectic clinics and ineffective communication among healthcare providers (Does and Mash, 2013).

The majority of the participants are Malay, and the general consensus was that the group mode of delivery of MY DEUMI has helped them to be more open, increase their awareness, gain more information, and acts as a mind opener to assist them in their self-care. Whereas, a case study of the Chinese people from Australia, China and Singapore suggested that they prefer a didactic, prescriptive teaching style and multiple education sessions to build trust (Choi *et al.*, 2017). Therefore, within the multicultural society that exists in Malaysia, it is necessary to consider cultural preferences when developing educational interventions for the community.

6.6.4 Limitations of the study

These included the fact that testing of the MY DEUMI intervention was conducted using a single-arm study with no control group and the follow-up was carried out at only 12 weeks. Therefore, it was not possible to determine whether any improvement in the outcome measure was due to the MY DEUMI intervention or confounding variables, which include other factors not covered in the study (McNamee, 2003), or whether the effect seen persisted over time, i.e. 6 months or more. However, it does give some information regarding the effect size that could be used to power a larger pilot randomised controlled trial.

Second, the small sample size limits the ability to generalise to a larger population, and we do not know whether this intervention is appropriate for all ethnic groups with T2DM in Malaysia, as the majority of the participants are Malay. The primary outcome measure of FBG was used, as it was not possible to arrange for HbA1c (% or mmol/mol) measure of glycaemic control, although the fasting plasma glucose (FPG)(mmol/L) can give an estimate of the overall glycaemic control, and is sensitive to HbA1c change (Bouma et al, Diabetes Care 1999). The reason for this was that the researcher was not authorised to perform phlebotomy which was categorised as a high-risk procedure, and the ethical committee (MREC) recommended the routine FPG (mmol/L) in the primary care lab as the best option to measure the outcome, where only non-penetrative procedure such as weighing, and questionnaire are allowed. Unfortunately, the HbA1c (% or mmol/mol) monitoring is only conducted once a year in the primary care clinics by the Ministry of Health Malaysia, while the FPG (mmol/L) is a routine blood investigation (at each follow-up consultation session) for people with T2DM.

Next, the secondary outcomes, self-efficacy and diabetes self-management, were self-reported, and restrict the quality of the data due to response bias, however, all questionnaires used were validated, and have an acceptable level of reliability. Bias may lead to overestimation of the effect, and questions might have not been answered truthfully (Mazor, Clauser and Gurwitz, 1998). Participants may be less likely to accurately report their diet pattern or physical activity level, driven by the ‘social desirability effect’ where a person tend to give response in a way that it is more acceptable socially, and sometimes the participants may overreport or underreport certain behaviours or attitudes (Tourangeau and Yan, 2007). Moreover, the interpretation of the questions may vary among different people.

Finally, this research was conducted in Malaysia by the researcher alone, so the fidelity assessment was self-conducted by the researcher. Although it was conducted with guidance (fidelity score sheet), a more robust evaluation would have been obtained if it were conducted by an independent assessor. The limitations of the study will be discussed further in Chapter 7.

6.7 Conclusion

Malaysians are known to behave politely and display a modest attitude among the community. This small feasibility study of the MY DEUMI intervention provides some support that a group-based diabetes education approach enhanced with psychological techniques can be potentially applicable, effective and acceptable for people with T2DM in Malaysia.

Feasibility was determined by the recruitment of people recently diagnosed with T2DM, the MY DEUMI intervention was successfully implemented, completion rates were adequate and there were no major technical issues affecting the delivery of sessions. The MY DEUMI intervention is associated with improvements in fasting blood glucose control, increased self-efficacy and diabetes self-management. In relation to a larger RCT, this intervention is likely to be acceptable among participants in the community centre setting.

However, if the programme were to be implemented in a primary care clinic setting, consideration must be given to the following: flexible or extended service time of the course or session (after office hours, during the weekend or bank holidays); marketing strategy to promote the intervention; reminder service; and outreach programmes where healthcare professionals run the intervention at the community setting rather than at the clinics. The MY DEUMI intervention may serve as a new way of reaching people with diabetes in the local community, as a way to improve diabetes self-management, health outcomes and well-being.

6.8 Summary

This chapter presents the results of the feasibility and acceptability testing of the MY DEUMI intervention. Findings from all phases of this thesis will be summarised in the next chapter. The strengths and limitations of the studies will be discussed. In addition, the implications of these findings for future structured diabetes education interventions, similar to MY DEUMI, for Malaysians newly diagnosed with T2DM will be elaborated.

Chapter 7 : Discussion

7.1 Chapter scope

The purpose of this final chapter is to integrate and bring together the findings from the different parts of this thesis. First, an overview of each chapter is presented, next, the research and clinical implications are discussed, and this is followed by the strengths and limitations of the research. Future directions for research are suggested based on the findings of this study, in the context of the wider literature on group-based psychoeducational interventions for people with T2DM.

7.2 Introduction: Overview of the chapters

This thesis presents the development of the MY DEUMI intervention, a psychologically enhanced structured group-based diabetes education for Malaysian adults newly diagnosed with T2DM, which was evaluated in a single arm non-randomised study. T2DM is a silent killer in Malaysia, where people die from complications such as cardiovascular disease, sepsis resulting from diabetic foot ulcers, as well as kidney failure, and not the disease itself. The human and financial cost are great. Therefore, interventions that support diabetes self-management, and prevent or delay the onset of diabetes complications are a priority.

This study is divided into three phases, (see Figure 61). Phase 1 (reported in Chapters 2, 3 and 4), consists of a systematic review, qualitative exploration and scoping study, all of which were used to develop the MY DEUMI intervention. Meanwhile, Phase 2 (reported in chapter 5), detailed the development of the intervention manual (written curriculum), through the compilation of findings from Phase 1. Finally, Phase 3 (chapter 6) reported the feasibility and acceptability study of the psychoeducational intervention (MY DEUMI), prior to a larger randomised controlled trial in Malaysia.

Figure 61: The phases of the MY DEUMI intervention.

Phase 1 (Chapter 1, 2,3 and 4)	A systematic review of behavioural and educational intervention for people with T2DM across the Asian Western Pacific (AWP) region.
	Conducting of in-depth face-to-face or audio-telephone interviews with adults with T2DM, to determine their specific educational needs.
	A scoping study to identify available materials/sources for manual intervention content.
	Revision and adaptation of behavioural theory, diabetes guidelines, psychological techniques and curriculum development theoretical framework.
Phase 2 (Chapter 5) Manual (Written curriculum) development of MY DEUMI for people with newly diagnosed T2DM in Malaysia	Developing a culturally suitable intervention for Malaysians comprising group motivational interviewing, structured diabetes education including hands-on activity, diabetes diary, and telephone follow up.
	The development of the written curriculum (format, content and structure).
Phase 3 (Chapter 6) Feasibility and acceptability study to evaluate the efficacy of the intervention	Single arm pre-test/post-test experimental study.
	Baseline and follow-up outcome measured at 3 months (12 weeks).
	Outcome measure: Primary: Fasting plasma glucose (mmol/L), weight (kg) and body mass index (kg/m ²); Secondary: Self-efficacy in self-management and Self-management practice.

Chapter 1

Chapter 1 set the scene and described the context for this thesis. It started with a description of T2DM. It gave an overview of the pathophysiology of T2DM. Following this, the disparities of risk factors for T2DM among Asians and Malaysian were discussed and contrasted with those of the Caucasians. Following that, the aims of diabetes self-management and non-pharmacological, surgical and pharmacological treatments were discussed. Details of cultural influences on the perceptions and management of diabetes were also explored. The final sub-section discussed the importance of diabetes self-management education, and its role in supporting people with T2DM to improve biomedical outcomes.

Chapter 2

The aim of Chapter 2 is to synthesise current literature regarding the effectiveness of educational and/or psychoeducational interventions for people with T2DM in the Asian Western Pacific (AWP) region through a systematic review. The AWP region includes Malaysia. The review identified twenty-one studies comprising sixteen RCTs, and fourteen studies using a group-based approach: 9 were RCTs, 2 were non-randomised studies and the last 2 were retrospective and observational matched cohort studies respectively.

Fifteen studies were carried out using educational techniques, either through a combination of didactic and facilitative teaching, or through only didactic teaching. While the other six studies were carried out principally using psychological interventions, and these have been implemented: CBT; motivational interviewing; or counselling therapy. Interventions with acceptable moderate effect sizes for HbA1c mostly included group-based educational interventions (50%, n=8), while studies

using group-based psychological approaches reported significant improvement in self-efficacy (67%, n=6). The systematic review concluded that group based DSME interventions underpinned by behavioural theory, extended contact hours (>10 hours) and practical sessions, should be considered when designing a DSME to maximise the potential benefits.

Chapter 3

The aim of chapter 3 is to conduct a qualitative study using semi-structured face-to-face and telephone interviews, to determine views and experiences of diabetes self-management of Malaysians with T2DM. Qualitative analysis revealed three major themes associated with diabetes self-management: (i) psychological issues (depression, anxiety and self-efficacy); (ii) social factors (shame/stigma and family support); and culture around food, such as small feast traditions, rice intake, as well as Malaysians' beliefs in herbal medicine and religiosity; (iii) environment (difficulties with diet management and ineffective support from healthcare providers). Findings from the systematic review and the qualitative study were then used to inform the development of the manual for the psychoeducational MY DEUMI intervention programme.

Chapter 4

The aim of Chapter 4 is to describe the manual development process for the MY DEUMI intervention. In addition to the findings from the systematic review (Chapter 2), and qualitative study (Chapter 3), this chapter discussed the relevance of the national guidance for a DSME by the AADE and the ADA. It applied a manual development process framework (Spady 1988) and incorporated psychological theory

such as the underpinning theoretical frameworks, the Theory of Planned Behaviour and the Social Cognitive Theory. Based on findings from the qualitative exploration in Chapter 3, motivational interviewing has been selected as the method of delivery. Meanwhile, the use of 10 hours of education/contact and hands-on activity were based on the conclusions from the systematic review in Chapter 2. Additionally, a scoping study, which was used to identify materials for the content of the MY DEUMI intervention manual, by exploring existing programmes in the United Kingdom and available resources, such as clinical guidelines and printed materials from local sources in Malaysia, was also described in this chapter.

Chapter 5

This chapter aims to present the format, structure and content of the MY DEUMI intervention. The background of the written curriculum was outlined. Motivational interviewing has been selected as the delivery approach to foster a therapeutic relationship, and support the potential for behaviour change according to the needs of the participants. Additionally, the sub-sections discussed the process of developing the written curriculum, based on the OBE concept: (i) Formulation of the learning outcomes; (ii) Specification of the characteristics of the learners or audience; (iii) Choice of the content of intervention (the blueprint); (iv) Formulation of the intended outcomes for each topic; (v) Outlining of the methods to achieve the intended outcome; and (vi) Specification of the evaluation strategies. Apart from that, a summary of face validity testing after the completion of the MY DEUMI intervention, was also outlined.

Chapter 6

The aim of Chapter 6 is to present the results for the feasibility and acceptability testing of the MY DEUMI intervention. Difficulties were identified with the recruitment of participants, and an alternative strategy was put in place due to the low response rate at the primary care clinics. A total of five (N=30) groups have participated in the study; two at the primary care clinic (n= 8), and three (n=22) at the community centre. Four of the five groups have attended it as a two half-day course, while the rest attended it as a 3-day course. At recruitment, the participants completed a consent form, and questionnaires, which was done before and 12-weeks after the completion of the MY DEUMI intervention programme.

Results suggest that the MY DEUMI intervention was feasible, as the minimum number of participants was reached, and the preliminary primary outcome concerning glycaemic control (fasting plasma glucose), and improved self-efficacy for diabetes self-management, were both achieved. The post-intervention feedback was obtained during the follow-up period, and face-to-face semi-structured interviews were conducted with 10 participants as part of the acceptability assessment. The participants indicated that the MY DEUMI intervention was acceptable to them. Findings from the main study (feasibility of the MY DEUMI intervention), and subsidiary studies (systematic review and qualitative study) will be discussed below.

7.3 Research implications

Following the development process of the MY DEUMI intervention (Phase 1 and 2), a decision has been made to discuss the findings according to the following 3 dimensions, as these are considered to be the novel elements of this new intervention: (i) delivery approach dimension; (ii) psychological needs dimension; and (iii) social dimension (cultural factors).

7.3.1 Delivery approach dimension:

Is DSME effective in optimising glycaemic control among Asians in the Western Pacific region? And what is the desired delivery approach?

As highlighted in Chapter 1, DSME is essential if people were to optimise their diabetes self-management. The question of how to deliver it in Malaysia was an important consideration while developing the MY DEUMI intervention (main study for this thesis). This decision was made based on the available evidence.

In Chapter 2, the main objective is to identify the current evidence base of available DSME intervention studies in the Western Pacific region. The review suggested that effective interventions (acceptable moderate effect size for glycaemic control) are available, and interventions using group-based approaches are the most effective at improving glycaemic control (improvement in the HbA1c level), where 4 out of the 8 group intervention studies had a moderate effect size (Cohen's $d > 0.5$), and were predominantly studies with high-intensity interventions (at least 10 hours of duration or more). Apart from that, there was an indication that interventions which integrated practical sessions (50%, $n=4$), exhibited moderate effect sizes for glycaemic control (HbA1c).

In a nutshell, the systematic review findings support the group-based delivery approach for the MY DEUMI intervention programme. It also suggested that hands-on activities serve to engage participants, and may potentially create an interesting educational environment to provide people with T2DM the necessary knowledge and skills for optimal diabetes self-management. Therefore, these were incorporated into the MY DEUMI intervention to enhance learning.

7.3.2 Psychological dimension:

Do Malaysians with T2DM require psychological support to assist them with their diabetes self-management?

In Chapter 3, the objective of the qualitative interviews is to explore the diabetes self-management experiences of Malaysian adults with T2DM, and to investigate their needs for additional support. The participants interviewed claimed that they experienced anxiety or depression, either at the time of diagnosis or at a later stage, especially for those who were having difficulty managing their blood glucose levels.

This is an important finding in the development of the MY DEUMI intervention, which was aimed at improving biomedical outcomes. Therefore, MY DEUMI aimed to consider the psychological needs of participants, in order to improve motivation and self-efficacy towards effective diabetes self-management. Additionally, Chapter 1 discussed the problem of obesity in Malaysia, a potentially modifiable risk factor for T2DM, which is associated with sedentary lifestyles, and therefore there is a need to develop strategies that increase activity as well as support weight loss. Lifestyle changes to increase physical activity and an improved diet are difficult for most people to achieve, and therefore, a psychological approach may help to improve motivation, increase self-efficacy, and support them to make these changes.

7.3.3 Social dimension:

Do Malaysians with T2DM have culture-specific requirements for structured diabetes education?

In Chapter 1, the disparities of T2DM risk factors for Asians and Malaysians were discussed, and the social and cultural influences on diabetes management were highlighted. However, despite this, the systematic review (Chapter 2) findings did not suggest specific cultural elements relevant to Asian (non-English speaking) countries that were incorporated into behavioural and educational interventions, aside from the fact they were delivered in the native language, and the questionnaires used were translated and validated.

However, the qualitative study in Chapter 3 revealed that one of the barriers perceived by the participants are cultural factors relating to the importance of rice, small feast culture, where both of these have proven to be a hindrance for these people to make effective dietary changes, as well as beliefs in herbal medicine and religiosity. Cultural sensitivity is considered to be an important aspect of a DSME and diabetes management, particularly in ethnically diverse communities, as recommended by the AADE (American Association of Diabetes Educators, 2012), who defined it as “the extent to which ethnic/ cultural characteristics, experiences, norms, values, behavioural patterns, and beliefs of a target population’s relevant historical, environmental, and social forces are incorporated in the design, delivery, and evaluation of targeted health promotion materials and programs.” (American Association of Diabetes Educators, 2012, pg 140). Moreover, in the AADE position statement, cultural sensitivity is divided into 2 dimensions: (i) surface culture; and (ii) deep culture. Table (7.1) displays the elements of each cultural sensitivity dimension.

Table 7.1: Cultural sensitivity dimensions: Surface and deep culture.

Surface culture	Deep culture
The intervention materials should consider familiar characteristics of the target population, such as language, food (includes type of food and eating habits), places and music.	The intervention should be developed through an understanding of the historical and psychological forces that influence the target populations, such as ethics (such as to offer food to others while eating), family ties (living within an extended family), ceremony, health and medicine (nature medicine or complementary medicine).

Adapted and modified from (Jarrold, 2013; Dube *et al.*, 2015).

Notably, the findings from Chapter 3 mostly refer to deep culture, and these are perceived as barriers for diabetes self-management among participants. For example, while attending any small feast party, it is an insulting for a guest to not accept or finish the food served, while as a host, it is considered disgraceful if you do not serve the best food or cuisine, which in most cases is high in fat, and are of sweet and savoury desserts among Malaysians.

Another example of deep culture is the belief in herbal medicine and its importance for Malaysian people, as well as how it is often used in addition to conventional medicine. The findings from the qualitative study suggested that both cultural sensitivity dimensions needed to be recognised and considered while developing the MY DEUMI intervention, to ensure its practicality and acceptability for Malaysians with T2DM. Meanwhile, for the main study of this thesis, it is noteworthy to discuss the findings regarding the feasibility and acceptability of the MY DEUMI intervention.

7.3.4 Is group structured DSME acceptable for people with T2DM in Malaysia?

The results from the testing of the MY DEUMI intervention indicate that group based structured diabetes education is acceptable for Malaysians with T2DM, according to the positive feedback received. Currently, only few people with T2DM are offered any form of DSME at the primary care clinics in Malaysia, either individually or in a group. For example, only 7 (24%, (N=30) of participants in this study attended (non-structured) diabetes education at least once in the clinic (not reported in the thesis). To date group-based diabetes education is very limited, and is mainly offered in the Malaysian private healthcare settings, as reported in a narrative review study regarding diabetes management models in Malaysia (Hussein *et al.*, 2015). The significant reduction in fasting plasma glucose level and weight among MY DEUMI participants, indicate that there are potentials for group DSME to improve biomedical outcomes.

MY DEUMI participants reported that there are differences in what they received from the intervention, compared to other diabetes education they have received previously. They described how the MY DEUMI intervention has encouraged them to reflect and discuss with their group members, as well as share and exchange ideas, thoughts and experiences. They claimed that this approach is more likely to create an informal educational environment, and group members are more open to discuss any issues or problems.

In a population cohort study implemented in Ontario, Canada, comparing patients who received group-based (n=12,234), versus individual DSME (n=55,761), and a combination of group-based and individual counselling (n=9,829), it was reported that the group approach allowed for discussions. Valuable experiences were shared, and this has led to improved motivation to optimise blood glucose control, and

they were more likely to attend for HbA1c monitoring (Odd Ratio (OR) 1.01, 95% CI [1.05, 1.15]), and less likely to develop hypo/hyperglycaemic attack (OR 0.54, 95% CI [0.42, 0.68]) (Hwee *et al.*, 2014). As applied in MY DEUMI and other studies (Steinsbekk *et al.*, 2012; Chrvala, Sherr and Lipman, 2016), as discussed in Chapter 2, a group approach allows participants to interact more and gain knowledge through experiences of others, and this may help them to deepen their understanding of T2DM, while promoting optimal diabetes self-management.

Moreover, sharing experiences can bring group members closer, and create a supportive environment that is likely to enhance learning. A review of four peer-group (non-health professionals) intervention studies to enhance diabetes self-management internationally (Cameroon, South Afrika, Thailand and Uganda), concluded that emotional and social support are among the key factors in assisting people with diabetes management (Speight *et al.*, 2011).

Peer support received may reduce emotional distress faced by people with diabetes, as claimed by some of MY DEUMI participants during the exit interviews. In support of this, in a peer coaching RCT (N=299; peer-coaching intervention group=148 and usual care=151) in San Francisco, USA, investigating the effect of peer support in diabetes self-management, in which groups were stratified according to their level of diabetes self-management and medication adherence, it was found that the peer coaching programme has successfully (large effect size) reduced the HbA1c level (-0.8% reduction) among participants who had low-medication adherence, compared to those in the good self-management group (Moskowitz *et al.*, 2013).

In contrast, an RCT in Hong Kong called the PEARL intervention (Peer Support, Empowerment, and Remote Communication Linked by Information Technology) (n=312) was compared with the JADE (Joint Asia Diabetes Evaluation) intervention (n=316), a web-based multicomponent quality improvement programme. The PEARL involved 30 peer coaches who had well-controlled T2DM, and were allocated 10 peers each, providing telephone coaching guided by a checklist. There was no statistically significant reduction of HbA1c (0.3%, 95% CI [0.12%, 0.47%], $p = 0.97$) (Chan et al., 2014). However, the PEARL programme participants demonstrated a reduction in hospitalisation (relative risks of 0.15 (95% CI, [0.07-0.34], $p < .001$), and less distress as measured by the 21-item Depression Anxiety Stress Scale for psychological distress (DASS-21) (mean changes 11.93, 95% CI [1.07, 16.79] vs 5.88, 95% CI [2.00, 9.76], $p = .03$), therefore suggesting that peer support may benefit people with T2DM who are experiencing DRD.

The MY DEUMI participants who were involved in the exit interviews claimed that the intervention has helped to reduce anxiety, improved their self-efficacy for their diabetes self-management, facilitated them to modify their lifestyle, and optimise their medicine intake. To conclude, a group DSME can be facilitative and assist people with diabetes self-management, and the group delivery method of the MY DEUMI intervention was acceptable to the participants.

7.3.5 Is it feasible to conduct group structured DSME at a primary care setting in Malaysia?

Generally, the overall result suggests that it is feasible to conduct MY DEUMI in a Malaysian primary care setting. However, there was a low recruitment rate at the primary care clinics compared with the recruitment from the community centres. Most of the dropouts occurred amongst participants from the primary care clinics recruitment pool 43% (6 out of 14), compared with the community centres at 21% (6 out of 28). Most claimed that the timing of the sessions was not suitable for them due, to their work or grandchildren care commitments. The researcher also found that it was difficult to be flexible when offering sessions at the clinic, as it was only open from 9 am to 5 pm, and there were only 2 days per week when a room was available. Out of the 6 dropouts (at the primary care clinic, only one person claimed to have problems with access due to a lack of transportation). This suggested that Malaysians accessing diabetes support from the primary care clinic live in urban areas, and therefore have access to transportation.

Specific barriers were identified regarding the implementation of the MY DEUMI intervention. Work and personal commitments were the main problems preventing potential participants from attending the intervention. Even though DSME is known to improve diabetes outcomes (Deakin, 2012; Khunti *et al.*, 2012; Krebs *et al.*, 2013); many people are still not convinced to attend it. Through DSME research, it has been identified that factors driving the low uptake are logistic barriers such as timing, cost and transportation (Winkley *et al.*, 2015).

As described in Chapter 6, the primary care clinic is known for its hectic and bustling environment, due to the walk-in system, and as a result, participants did not feel relaxed within the setting. Therefore, this had an impact on the way MY DEUMI and other education sessions were delivered. The participants also claimed that there was a lack of promotion or marketing from the healthcare professionals (nurses and doctors), and no posters to promote the potential benefits of diabetes education in the primary care clinics. In a recent systematic review of 12 quantitative and qualitative studies of barriers to attending diabetes education, it was revealed that in addition to logistic barriers, another issue highlighted was that some people perceived that diabetes education is not helpful in their disease management (Horigan *et al.*, 2016). Therefore, extensive and on-going marketing may educate people with T2DM on how DSME could benefit them in their diabetes self-management.

7.3.6 Was the delivery method incorporated into the MY DEUMI intervention beneficial to participants?

Psychological problems such as anxiety or depression are common among people with diabetes, and these problems are associated with poor glycaemic control. A meta-analysis of studies investigating the association between depression and metabolic control revealed that depression is cross-sectionally associated with hyperglycaemia ($Z=5.3$, $p< 0.0001$) (Lustman *et al.*, 2000). Furthermore, in a systematic review of anxiety problems among people with diabetes, which included studies with any clinically relevant anxiety measure ($n=18$: 5 were controlled while 13 were uncontrolled), it was indicated that at least 14% of people with diabetes had generalised anxiety disorder, while 40% presented with elevated anxiety symptoms (Grigsby *et al.*, 2002).

The qualitative study in Chapter 3 also highlighted that anxiety had a negative impact on motivation for diabetes self-management, and many people who were interviewed spoke about feeling depressed because of diabetes. This finding was central to the development of the MY DEUMI intervention, which sought to support participants' psychosocial needs to promote effective diabetes self-management. We know from case studies (N=3) exploring the impact of psychological components in diabetes care that psychotherapy helps people with diabetes to accept the diagnosis, promote behavioural change and reduce distress (Feifer and Tansman, 1999).

From the exit interviews, the majority of the MY DEUMI participants claimed that the interactive delivery approach (motivational interviewing) has opened their minds and allowed them to understand their diabetes better than before. Moreover, reflective and discussion sessions within the programme created more awareness, and prepared them to consider lifestyle change, more than any other diabetes education they had previously attended. This was supported by a narrative systematic review of 13 studies (quasi-experimental, cohort, case-control and pre and post-test studies, meta-analyses, systematic reviews and literature review), which concluded that motivational interviewing is associated with improved psychological functioning and lifestyle modifications among people with chronic diseases (Coyne and Correnti, 2014). Furthermore, a systematic review of RCTs (N=14) specific to T2DM, demonstrated that motivational interviewing was most effective on improving dietary behaviour and weight loss compared to other outcomes (Ekong and Kavookjian, 2016).

7.4 Clinical implication

7.4.1 The challenge of incorporating psychosocial and behavioural support into T2DM management

Both the group-based and psychological techniques (motivational interviewing) employed as the delivery method for MY DEUMI intervention were valued by the participants, as demonstrated by the exit interviews. There were improvements in blood glucose control as measured by the fasting plasma glucose between baseline (mean = 9.36 mmol/L, SD = 2.52) and follow-up (mean = 7.82 mmol/L, SD = 1.57) post-intervention (mean reduction 1.54, 95% CI [0.67 to 2.42] mmol/L, $t(29) = 3.618$, $p < 0.001$). Apart from that, there were improvements on measures of diabetes self-efficacy pre- and post- MY DEUMI intervention.

Whilst this study was not powered to detect statistically significant changes in outcome variables, these findings are generally supportive of incorporating psychosocial and behavioural support in diabetes care. Behaviour modification is a must for people diagnosed with T2DM, and is often considered a burden along with work, family responsibilities and other life goals. The American Diabetes Association in a consensus report recommended that diabetes health professionals should be equipped with evidence-based behavioural change consultation techniques to support their clients effectively (Marrero *et al.*, 2013).

A phenomenological study through 7 focus group discussions (FGD), exploring the experiences of self-management among people with diabetes (type 1 and type 2) have shown that people with diabetes need to get a well-balanced lifestyle change with support from family and friends in an environment where it is socially acceptable to make the necessary behavioural change. When these are in place, people gain self-confidence and self-efficacy (Rosenbek Minet *et al.*, 2011). Therefore, health

professionals who are competent in counselling techniques may recognise their client's issues, especially diabetes-related distress (DRD), so that they can support them to improve self-confidence and efficacy.

Being diagnosed with T2DM can lead to DRD, such as anxiety and depression, which can then detrimentally impact glycaemic control (HbA1c). A prevalence study of DRD in Malaysia reported high levels of self-reported DRD (17-item Diabetes Distress Scale (DDS-17)), and the prevalence rate of 49.2% was higher than previous studies conducted in Europe (14.7%) and the US (12%), but comparable with data from China (64%) and Iraq (51.8%) (Chew *et al.*, 2017). Therefore, we know from these studies that the DRD rates in Malaysia are high, and our finding that emotional distress was commonly reported in the qualitative study (Chapter 3) supports this.

A potential explanation for the higher DRD rates in Malaysia could be due to having insufficient knowledge and skills to enable effective diabetes self-management. This 'not knowing' what to do may lead them to follow advice from others, and generally get confused with mass opinions. Some people are easily overwhelmed with recommendations that may lead to ineffective self-management, such as being confused with regard to diet, or not adhering to medication due to unhelpful illness beliefs. It is crucial for people with diabetes to gain reliable and beneficial information to assist them in their diabetes self-management.

To conclude, psychosocial and behavioural support for people with T2DM from health professionals is essential to increase motivation, and promote the uptake of knowledge and skills to improve diabetes self-management.

7.4.2 Recommendations for health professionals and diabetes educators in Malaysia

In the MY DEUMI feasibility study, one of the barriers faced was recruitment for the sessions in the primary care clinic. The main reasons given by (potential) participants were the unsuitable timing of the sessions and family commitments. It is crucial to develop a well organised DSME programme for Malaysians with T2DM, to prevent and/or delay progression of costly complications. Thus, flexible delivery time of DSME at the primary care clinic needs to be considered to get buy-in from people with T2DM, to improve their understanding of the disease and promote better diabetes self-management.

As the recruitment target via the primary care clinic was not met, an alternative strategy was implemented by approaching community centres. This approach was feasible, and the attendance rate was at 80%, where 22 participants out of 28 agreed participants attended the sessions, compared with the attendance rate of 57% at the primary care clinic (8 participants out of 14 who initially agreed to participate). As people recruited via the community centres already knew one-another, there was an existing relationship or rapport, which is known to create a supportive environment for learning to take place, as it strengthens the sense of belonging and shared values (Mengistu, 2006). Along with the supportive environment and sharing the same diagnosis, participants may feel more comfortable discussing their problems in a more relaxed and informal atmosphere. As a result, this may ease any emotional distress and reduce the impact of stigmatisation faced by many people with diabetes. Finally, the community centres were more flexible when it came to room availability, and therefore more people were able to participate in the MY DEUMI intervention.

The role of the community centres in engaging people with T2DM in the DSME programme needs to be recognised and developed in light of the advantages identified as part of this PhD thesis as an alternative venue to deliver DSME with the additional benefits of existing social support networks. This can be achieved by bridging the primary care clinic services and the community centre resources to promote DSME. An RCT (N=130) investigating the effect of community-based, culturally sensitive combined with health-empowerment intervention for people with T2DM, demonstrated significant improvement of BMI (kg/m²), blood pressure and DRD; and the participants found it to be practical and patient-centred (especially the peer-sharing activities) (Tucker *et al.*, 2014). The primary care clinic has the resources to provide diabetes education, although not yet psychologically enhanced DSME, while the community centre can offer greater access as well as social networks to the local people. Additionally, and uniquely, DSME could be combined with commercial weight managements, personal trainers or coaching programmes that are currently in demand among Malaysians.

Trust in information received from health professionals is important. Trust is quickly built among Malaysians once they feel they are treated like a family member. A qualitative study (12 in-depth interviews among people with T2DM and 3 focus group discussions among 13 health professionals) conducted in a primary care setting of Selangor, Malaysia (Low, Tong and Low, 2016), suggested that social networks (family, friends and health professionals) were important influences on health-seeking behaviour. Therefore, people with T2DM are potentially easily influenced by information received from trusted social networks, and establishing good relationships with health professionals is necessary to optimise diabetes care in the Malaysian primary care setting. This is similar to a report of a qualitative study of Mexican

Americans that a strong sense of family values between people with diabetes and health professionals have encouraged behaviour change and adherence to treatment (Plasencia *et al.*, 2017). Thus, health professionals need to engage people with diabetes and build supportive relationships, to provide them with reliable information to enhance diabetes self-management.

From the qualitative study in Chapter 3, some participants expressed their concern regarding ineffective support from health professionals, and this was seen as a barrier as they then lacked motivation to self-manage their diabetes. The strategy of patient empowerment has long been promoted to support people with diabetes self-management (Anderson and Funnell, 2010), and therefore establishing and maintaining a positive relationship between health professional and a person with diabetes is central to this philosophy.

Extensive collaborative management between GPs, physicians, diabetes nurses, dietitians and diabetes educators is also another important strategy that need to be considered for implementation in Malaysian healthcare setting. For example, in Italy, a feasibility pre-post study named Project Leonardo (N=1,160), was designed to empower people with diabetes to be more pro-active in their self-management, by introducing care manager nurses to collaborate with the GPs', and work closely with patients on diabetes self-management. The findings demonstrated a significant change in self-efficacy, and an improved glycaemic control, as well as being feasible for the participants (Ciccone *et al.*, 2010). As a result of the significant positive outcomes, Project Leonardo was recommended to the GP group practices to provide this type of collaborative management (care manager nurse and GP), and it was extended as an outreach programme to assist patients' diabetes self-management. Apart from the collaborative management, there is a need for an advanced specialist role of diabetes

managers in Malaysia, who are specifically in-charge of diabetes educators in the healthcare setting. It is crucial that this independent role with an upgrade of knowledge and qualifications, to ensure quality and to improve any DSME or diabetes education delivered in various type of settings. However, the possibility of resistance to change the approach of service delivery must be anticipated. In order to reduce the resistance of change, action research or participatory research may empower health professionals in Malaysia, as well as triggering their interest on a better approach, sense of responsibility, and ownership in any diabetes education interventions

Much of the content in the MY DEUMI intervention can also be applied to other long-term chronic conditions, such as cardiovascular disease, hypercholesteremia and hypertension, where lifestyle change and self-management skills are required. Due to the fact that lifestyle changes are long-term in nature, another important clinical implication is the availability of on-going support, to ensure that lifestyle changes are sustained among people with T2DM. Most research in this area focuses on short-term interventions, which are proven to improve diabetes self-management, but people with diabetes may struggle to maintain lifestyle changes over a long period of time, without follow-up sessions. For example, the 3-year follow-up evaluation of the DESMOND trial revealed that a one-time diabetes education intervention demonstrated no significant difference in the metabolic outcome and lifestyle changes, except that the participants maintained their understanding of the disease (Khunti *et al.*, 2012).

7.5 Will Malaysia roll-out DSME?

Malaysia is a developing country progressing well socioeconomically, which in turn has impacted the lifestyle and dietary patterns of the population; and with it increased the prevalence of T2DM disease, its associated complications and mortality. In a recent narrative review regarding diabetes management models in Malaysia, it was reported that the Malaysian government is attempting to tackle this health threat by putting in resources to improve diabetes care. The review suggested that more focus should be given to developing clinical information systems, self-management support (DSME), and community resources (Hussein *et al.*, 2015).

The MY DEUMI intervention gives an added value to research on DSME that has been previously conducted in Malaysia, as it focuses on people newly diagnosed with T2DM and uses a group-based approach. An RCT (N=164) conducted in Malaysia aimed to assess the effectiveness of brief DSME (two face-to-face individual education sessions and a telephone follow-up), revealed significant improvement in HbA1c level ($p=0.03$) (Tan *et al.*, 2011). Meanwhile, a non-randomised pilot study (N=88) of culturally tailored diabetes education intervention based on the Health Belief Model (HBM), indicated that there was a positive outcome for each construct of the HBM. However, there were major limitations, as the study was not based in the clinical or primary care clinic setting, and did not measure any biomedical outcomes (Ahmad *et al.*, 2014).

Another recent study that included a quasi-experimental pilot study (N=52) investigating a self-efficacy education intervention amongst nursing home residents with diabetes, has demonstrated significant improvement of fasting blood glucose level, quality of life and foot-care behaviour. However, the findings were of limited

generalisability, due to its non-RCT design, and the primary outcome was on diabetes foot care (Ahmad Sharoni *et al.*, 2017).

Resource Issues

Until recently, research testing DSME (listed above), including the MY DEUMI intervention in the Malaysian setting have primarily reported positive outcomes in terms of biomedical measures, such as HbA1c (% or mmol/mol), FPG (mmol/L), blood pressure (mmHg) and self-efficacy. These therefore indicate that Malaysians are ready to embrace novel educational methods, with its flexible and interactive delivery approaches.

However, there is a lack of trained health professionals, especially diabetes nurses within the diabetes multi-disciplinary team, available to deliver these interventions. As a result, there is no national guidance for health professionals involved in diabetes care, leading to inefficiency in the delivery of diabetes education. More training is needed to produce more certified health professional in diabetes care, to fill this resource gap, as well as to improve the competency and skillset among them. Communication skills and counselling techniques are also important skills for health professionals to acquire, to enable them to support people with diabetes psychologically.

Addressing stigma

In addition to preparing health professionals to improve DSME, stigma is another problem identified as part of this thesis (see Chapter 3). Stigma demotivates people with their diabetes self-management, and strategies are needed to overcome it. These are likely to be needed at a national level, and therefore research to develop and

implement strategies to change Malaysians' views towards people with diabetes and reduce stigmatisation should be considered.

Empowering people with diabetes to improve their knowledge and skills in diabetes self-management is difficult without proper support from the community and environment. However, results from the qualitative study in Chapter 3 would recommend involving support from family members or close friends, to increase motivation and to maintain their efforts in diabetes self-management.

Newer technologies

Another option for Malaysia to consider are the newer technologies. M-health is an area of telemedicine evolving from the advancement in the telecommunication technology. People diagnosed with T2DM in Malaysia are generally aged of 50 years or more (Mustapha and Azmi, 2013), and a recent survey by Nielsen smartphone user suggests around 36% of people who use smartphones are aged 30 years and above (Vserv, 2016). Therefore, the use of M-health technology could be beneficial for behavioural change, and opportunities should be explored as part of the delivery approach for DSME.

The mobile applications can be used to record medication intake, blood glucose level monitoring and weight watching. In support of that, a systematic review suggested that mobile applications integrated with clinical guidelines are required for in the future (Chomutare *et al.*, 2011). A Cochrane review indicated that mobile phone-based intervention is more likely to give a better impact compared with computer-based DSME intervention (Kingshuk *et al.*, 2013).

Furthermore, social media is becoming more popular among Malaysians and utilising its potential for lifestyle modification or social support should be considered. For example, shared decision making between health professionals and clients could be facilitated via social media platforms such as Facebook or Messenger, via mobile phone application to agree on medical management or to answer queries or issues. However, data security issues must be considered as paramount. Interactive and graphics tools and computer-based software allow people with diabetes to retrieve a great deal of information that may support their diabetes self-management. These kinds of visual aids could be encouraged among diabetes health professionals who deliver diabetes education to improve their understanding of the disease process and promote good diabetes self-management.

7.6 Strengths and limitations of the study

7.6.1 Strengths of the study

The novelty of the MY DEUMI intervention format

Malaysia has a national plan for diabetes, which involves the enforcement of sugar policies (zero subsidies for sugar), and an increased availability of healthy food and specialised diabetes care offered to the population. However, there is still limited availability of diabetes self-management education (International Diabetes Federation, 2014).

This MY DEUMI intervention was targeted at people newly diagnosed with T2DM, as recommended by the AADE, and as discussed in Chapter 1. Apart from that, Malaysians diagnosed with T2DM in their early 50s, and uncontrolled blood glucose levels are more prevalent in people aged less than 60 years where 72.3% of the registered patients in the local primary care clinics have HbA1c > 6.5% (Mahmood, Daud and Ismail, 2016). Therefore, there is a need for Malaysians to receive information regarding diabetes to increase awareness and knowledge, to support optimum diabetes self-management at the earliest point from diagnosis.

The strengths of this thesis are: (i) this thesis tested a novel structured group diabetes education intervention, the MY DEUMI intervention, for people recently diagnosed with T2DM in Malaysia; (ii) the MY DEUMI intervention incorporates psychological techniques (motivational interviewing); and (iii) MY DEUMI was designed to have cultural relevance to the local population. MY DEUMI also combines education with hands-on activities and interactive games.

In summary, some of the benefits of the MY DEUMI intervention include:

- i. Evidence-based content: The content and information of the intervention manual were adopted mainly from well-established clinical guidelines available in Malaysia. It was also underpinned by behavioural change theory, which is proven to be an important framework in diabetes education to empower people to self-manage their diabetes effectively.
- ii. Two-way-communication: The delivery approach involved motivational interviewing technique, and allowed the participants to be more open to discussing and reflecting with the group members and the facilitator. The reflection sessions have given the participants an opportunity to share their experiences with others, to aid group learning and to discuss topics relevant for diabetes self-management.
- iii. The interactive features: The intervention utilises interactive games in most of the sessions, as well as embedded reflection sessions. Real food packaging and quizzes are some of the features available throughout the programme. Additionally, posters from the Ministry of Health Malaysia and a diabetes diary workbook helped to make the sessions more appealing and interactive.

Detailed early work development

The MY DEUMI intervention was developed in accordance with the MRC framework (Craig *et al.*, 2008): specifically, the development and feasibility/piloting phases. These two phases were conducted rigorously using both quantitative and qualitative strategies, involving Malaysians newly diagnosed with T2DM.

First, a systematic review was completed with the aim of assessing the effectiveness of educational and/or psychological DSME programmes for people with T2DM in the Asian Western Pacific Region. Secondly, people recently diagnosed with T2DM were key to develop the psychoeducational programme by exploring their

views and experiences of diabetes self-management. Moreover, their needs for DSME were discussed and the information gained was essential during the development of the MY DEUMI intervention to make it culturally relevant. The manual for the intervention was then developed by integrating findings from the systematic review, qualitative exploration, and materials available locally in Malaysia. It was then evaluated via a feasibility study and the outcome including process measures were elicited from the participants with T2DM in primary care. Due to time constraints, it was beyond the scope of this thesis to conduct a more extensive project. However, this study does suggest that the MY DEUMI intervention has the potential to be effective, and is feasible and acceptable for people with T2DM in Malaysia.

The implementation of a process evaluation framework enables comprehensive assessment of the main elements of the MY DEUMI intervention, and may serve as a helpful guide for a future larger scale trial. Moreover, the development of the MY DEUMI intervention highlighted the importance of facilitator-participants relationship, sometimes termed as therapeutic alliance. The interactive motivational delivery approach and group-based education were considered important and acceptable for people newly diagnosed with diabetes in Malaysia. The exit interviews aimed to assess the acceptability of the MY DEUMI intervention from the participants' perspective, and to ensure that the evaluation of the implementation was robust. Apart from that, the manual for the MY DEUMI intervention was developed specifically to work with local cultural values. This specific measure helped to increase motivation, and the participants have found it helpful for their lifestyle modification/behavioural change. Thus, the reliable cultural content and local resource materials facilitated the acceptance of the MY DEUMI intervention, while promoting a deeper understanding of T2DM, which may help people with the condition to optimise their diabetes self-management.

7.6.2 Limitations of the study

Design of the feasibility study

The main limitation is the research design. The randomised controlled trial (RCT) is considered as the gold standard in complex intervention evaluation research (Moore *et al.*, 2015). However, considering the issue of limited funding and expertise, an RCT is not always possible within a short time-frame. An absence of a control group could be seen as a significant limitation of the feasibility study, conducted as part of this thesis. There are reasons for this:

- i. The diabetes nurse and physician-in-charge who assisted with recruitment claimed it would be difficult to recruit a sufficient number of participants in a two-group design, due to the specific inclusion criteria (recently diagnosed) within the time-frame given.
- ii. The seminar room at the primary care clinic was only available during working hours (9.00 am until 5.00 pm) for 1 or 2 days in a week, and this has limited the number of MY DEUMI interventions that could be delivered.

Therefore, further research is required to evaluate the effectiveness as well as the potential confounding variables that may give specific impact to the outcome. This would be implemented in an RCT.

The MY DEUMI intervention study was conducted in an urban and sub-urban region of southern Malaysia. Hence, there is a possibility that in rural areas among people with different socioeconomic backgrounds and lifestyle (for example choice and availability of food), there may have been a difference in the feedback for the MY DEUMI intervention. Therefore, the qualitative study and small feasibility study may

have been more culturally relevant if it had included Malaysians living in the rural area with different backgrounds and available resources.

Self-reporting tools

It has not been possible for research using human subjects to completely exclude the risk of Hawthorn effect. Therefore, precautions should be taken to minimise this unavoidable bias. Self-report measures were used in the MY DEUMI feasibility study to measure self-efficacy and diabetes self-management. Participants might not answer the questions genuinely if they know that they are being observed. Therefore, the self-report measures used were the validated questionnaires to minimise this limitation.

The short follow-up for the MY DEUMI feasibility study

The outcome data for the feasibility study was collected at 12 weeks post-intervention. It was beyond the scope of this thesis to have a longer follow-up, due to time and funding limits associated with a PhD research. Specifically, there was a need to develop the MY DEUMI intervention manual, creating some interactive games for the programme from scratch (e.g. scoping study, intervention manual and diabetes diary workbook). The duration of the study was not sufficient to assess the effects of the biomedical outcome; for example, change of lifestyle and BMI. The twelve-week follow-up period has allowed the researcher to determine if there was an immediate impact of the intervention. An RCT with a 1 to 2-year follow-up would be recommended, to determine whether the MY DEUMI intervention can bring about significant improvement in diabetes self-management over the life course. However, this may also involve additional sessions or refreshers.

Gender of participants

A significant proportion of the participants in the feasibility study and exit interviews were females (70%= feasibility study; 90%= exit interviews). This was unplanned, and there are possibilities for the results to be biased towards females. Similarly, the findings from the qualitative study that were used to inform the development of the intervention may reflect the needs and barriers of Malaysian females with diabetes, as 60%, which is 10 out of 17 of the participants were female. Likewise, the high proportion of females and therefore the conclusions drawn from the feasibility and acceptability testing (process assessment and exit interviews) mainly captured the opinions from one gender (female). This is possibly due to the fact that females are more likely to seek help for their medical health as compared to males. This is supported by a cross-sectional study of patients attending GPs in the UK, where it was reported that on average men accessed and consulted less often than women, between the ages of 16 and 60 years (Wang *et al.*, 2013).

It was not possible to identify the reason why men were less interested to participate in the MY DEUMI intervention. Consequently, this prevents the opportunity to explore and understand the males' perspective, as well as their particular needs and requirements. It is well known that health-seeking behaviour is different among males compared to females. In a qualitative research project conducted for a London council, in order to develop a new intervention for men's health, aimed to review men's health seeking behaviour and use of internet and involved semi-structured interviews and focus groups (N=57), it was found that masculinity was the main factor that negatively impacts men's health seeking behaviour, although men would seek health information from the internet (Bogle, 2013).

Additional, findings from the study indicated that men get frustrated with not being able to book appointments and being treated in an unfriendly way. None of this applied to participants in the MY DEUMI intervention. Therefore, the reasons are likely to be complex. Another systematic review of quantitative and qualitative studies (N=41) on health seeking behaviour in men demonstrated that the barriers for men to seek help in medical are due to embarrassment, anxiety, hesitance to express health concern and poor communication with health care professionals (Yousaf, Grunfeld and Hunter, 2015).

Problem with fasting plasma glucose level as the primary outcome measure

Finally, the MY DEUMI intervention feasibility study did not measure glycosylated haemoglobin (HbA1c) as the primary outcome measure, owing to logistic problems described previously. Nevertheless, fasting plasma glucose is not ideal but it can be used as an alternative to HbA1c, where plasma glucose concentration is a reliable acute parameter while the HbA1c level is a long-term reflection of glucose control (Bouma *et al.*, 1999).

Most diabetes guidelines recommend using the HbA1c to measure glycaemic control (Reddy *et al.*, 2012), however, there are advantages and disadvantages of using the HbA1c when it is used to diagnose diabetes. According to Bonora & Tuomilehto 2011 (Bonora and Tuomilehto, 2011), in a literature review conducted to illustrate the pros and cons of HbA1c and diabetes metabolic markers, it was concluded that A1c assay is an expensive method, whereas the fasting plasma glucose is a more sensitive method to detect impaired glucose metabolism, therefore to avoid potentially missing diagnosis, they suggest that both diagnostic approaches are reasonable and acceptable.

7.7 Overall conclusion

The central objective of the research project presented in this thesis is to develop and evaluate a group structured diabetes education programme enhanced using motivational interviewing for people recently diagnosed with T2DM in Malaysia, the MY DEUMI intervention. With this intention, research into diabetes educational and behavioural programmes from the Asian Western Pacific Region was systematically reviewed. Additionally, a qualitative study was conducted to determine views, experiences and needs of Malaysian adults with T2DM with regard to diabetes self-management. Following that, the process of the manual intervention programme development was described. It involved the compilation of findings from the systematic review, the qualitative study, which also determined the barriers and facilitators towards good diabetes self-management, and a scoping study to locate available materials. The MY DEUMI intervention was developed using motivational interviewing as the delivery approach with features such as hands-on practice, interactive games and quizzes.

Feasibility, preliminary outcomes and acceptability of conducting the structured diabetes education programme (MY DEUMI) among people with T2DM in the primary care clinics and community centres was conducted. The results were convincing. Recruitment, attrition and completion of the MY DEUMI intervention programme were the components investigated for feasibility. Not only was it feasible, positive findings for the primary outcome measure of the fasting plasma blood glucose level, secondary measures of self-efficacy and diabetes self-management level were demonstrated. Additionally, promising results were also obtained for the acceptability

testing of the MY DEUMI intervention programme, in which most participants claimed it was a helpful, engaging and it has been an interesting experience for them.

It is suggested for future research to explore further the potential effectiveness of the MY DEUMI intervention, and make the times of its availability more flexible and with some added information technology-mediated features. In essence, this thesis reports the preliminary evidence for a novel group structured diabetes education programme, featuring motivational interviewing for people recently diagnosed with T2DM in Malaysia. All things considered in the outcomes from the MY DEUMI feasibility study suggest, this psychoeducational programme could be a promising new treatment that should be tested in a larger RCT.

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APPENDIX A



MALAYSIAN DIABETES EDUCATION PROGRAMME USING
MOTIVATIONAL INTERVIEW (MY DEUMI)
Structured Group Education Curriculum manual



Foreword

This manual was produced to underpin the MY DEUMI educational programme which has been designed to improve self-management among people with type 2 diabetes mellitus (T2DM). It uses the techniques of Motivational Interviewing (MI) therapy to guide the delivery of the programme and to encourage lifestyle modification. We hope that this client-centred approach will be acceptable to people with T2DM in Malaysia and help health professionals to deliver support their patients. Please find enclosed the manual for MY DEUMI study. The content of the manual belongs to the MY DEUMI study and should not be circulated outside of the study. We thank you for your help in delivering the MY DEUMI programme.

The MY DEUMI study workbook and curriculum was written by
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How to use this manual

This manual includes the information you need to deliver the 10 educational sessions and have fun while doing it. Each session covers a different topic and includes a hands-on session on diabetes health. Key learning notes help you to provide the information for each session.

Overview of Motivational Interviewing.

Motivational interviewing supports behaviour change by strengthening the person's own motivation and commitment to change (Miller and Rollnick, 2013). Most of discussion in this programme uses specific MI communication style and prior to delivery, the facilitators require training and to be assessed for competency.

The acronym used for this style communications is (OARS) and is elaborated below:

- ❖ Open ended question: to encourage elaboration and consideration.
- ❖ Affirmations: to foster positive feelings in the participants
- ❖ Reflections: the facilitators will be mirroring back the participants respond to build rapport and trust.
- ❖ Summary: to help the participants look at the bigger picture.

Introduction 1: Are you ready?

Session : Introduction 1
Topic : Are you ready?
Time : 30 minutes
Theory : Not applicable
Aims

- Offer a warm welcome into the study.
- Assess their readiness for the programme.
- Identify their expectations of the programme.
- Understand the outline of the programme.

To conduct this session, you will need:

- * MY DEUMI manual
- * Ice-breaking games sheet
- * Name tags
- * Whiteboard or paper flip chart
- * Reward

Detailed lesson plan (Introduction 1)

Time allocation	Section	Facilitator activity	Notes
5 min	Introduction	<ul style="list-style-type: none">* Introduce self* Explore each person his/her name and nickname.* A warm welcome to the study.	Distribute name tag
5 min	Study outline	<ul style="list-style-type: none">* Congratulate everyone who came by showing an interest in learning more about self-management.* Introduce the programme outline.* Elicit group agreement.	Handout see Appendix 1: programme outline
	Ground rule	<ul style="list-style-type: none">* We need to agree to keep other people's experiences and input confidential and not to judge others.* In this programme we use a motivational approach. We will avoid confronting one another's life. We'll facilitate through listening and supporting each other here. We may have knowledge but ultimately if there is any changing to be done, you will be the one to do it.	
5 min	Hope	<ul style="list-style-type: none">• Explore: What do you hope to learn in this programme?	Write on flipchart. Review and reflects using OARS whenever suitable.

Introduction 2: Towards an effective self-management

Session : Introduction 2
 Topic : Towards effective self-management
 Time : 30 minutes
 Theory : Not applicable
 Aims

- Increase optimism and confidence about joining this programme.
- Elicit understanding of T2DM and risk factors.

To conduct this session, you will need:

- * MY DEUMI manual
- * Quiz questions
- * Whiteboard or paper flip chart
- * Refreshments

Detailed lesson plan (Introduction 2)

Time allocation	Section	Facilitator activity	Notes
5 min	Introduction	* Elicit group agreement to continue the programme	
5 min	Sharing moments	* Explore: Who would like to share the risk factors that might important to address? Tell us more about it. * Explore: How other's think of (name) thought? * We discussed T2DM risk factors. * Explore: What do you think you could do to control your blood sugar levels? Prompts: activity, lifestyle * The information given is evidence-based, however you should decide yourself the possible changes that might benefit you.	Write the answer on the flip chart. Provide information see Key learning points i. Review and reflect using OARS whenever suitable Provide information see Key learning points ii.
10 min	Eliciting change talk	* Explain: It's quite normal to have mixed feelings at this stage. You might think some change is good and you might have made it and on the other side it seems hard to comply or to change habits. * So, let's have a think. If you make some changes to your lifestyle what benefits do you think you would notice?	Write on flipchart. Review and reflect using OARS whenever suitable.
10 min	Individual assessment	* Answer the Diabetes knowledge quiz questions. * We are not judging your knowledge your answers may help us to deliver information at the optimum level.	Handout see Appendix 4: Diabetes knowledge question

Key learning points i

The following increases your risk of T2DM:

First degree relative with diabetes (parents, brothers and sisters)

1. History of cardiovascular disease (CVD)
2. Hypertension (BP \geq 140/90 mmHg or on therapy for hypertension)
3. Impaired glucose tolerance or impaired fasting glucose on previous test
4. Having abnormal blood fats levels (HDL-good cholesterol less than 1.0mmol/L for men or less than 1.3mmol/L for woman or triglyceride level 1.7mmol/L or above)
5. Being overweight or obese (BMI 23 or 28 and above- for Asians)
6. Excess fat around abdomen (waist circumference of 90cm or larger for man and 80cm or larger for woman)

7. Women delivered baby more than 4kg and history of gestational diabetes (GDM)
8. Women with polycystic ovarian syndrome

Key learning points ii

The following helps to control your blood sugar level:

Eating a healthy diet

1. Being more physically active
2. Losing weight (if you need to) and maintaining a healthy weight
3. Reducing your cholesterol
4. Keep calm and manage stress

Key learning points iii

Benefits of lifestyle modifications:

1. Lowering blood pressure
2. Strengthen immune system
3. Reducing risk of CVD
4. Maintaining weight
5. Increase energy

Session 1: What is diabetes?

Session : Session 1
 Topic : What is diabetes?
 Time : 60 minutes
 Theory : Social cognitive theory (SCT) and Theory of planned behaviour (TPB)
 Aims

- Elicit understanding of causes, symptoms and complications of T2DM.
- Increase awareness towards effective self-management.
- Goal setting; how; why

To conduct this session, you will need:

- MY DEUMI manual
- Figure 1
- Figure 2
- Post it notes
- Whiteboard or paper flip chart
- Refreshments

Components of theory (Session 1)

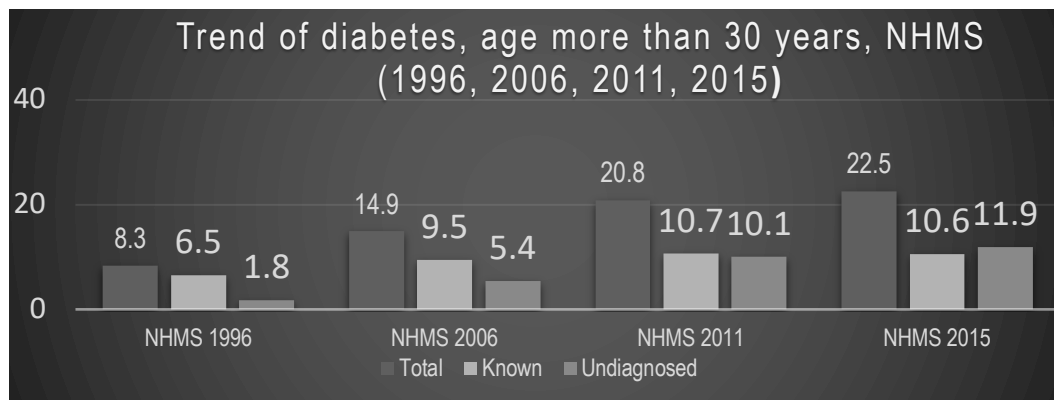
Theory	Components of theory	Specific aspects of the theory	Activities
SCT	Cognitive factors	Elicitation of knowledge	Lively discussion: Primary goal of self-care
		Self-efficacy	Goal setting
	Environmental factors	Access in community	Lively discussion: Available resources
		Ability to change own environment	Identification of own ways towards behavioural modifications
TPB	Subjective norms about the behaviour	Opinion of referent others	Sharing of complications experience by group members
	Attitudes toward the behaviour	Evaluation of the behaviour	Lively discussion: Reason to reduce T2DM complications

Detailed lesson plan (Session 1)

Time allocation	Section	Facilitator activity	Notes
5 min	Introduction	* Elicit group agreement to continue programme * Explore: What is your opinion of this poster from Ministry of Health Malaysia	Visual aid: Appendix 5: Poster (Malaysians at risk!) . Provide information see Key learning point 1.1 .

Time allocation	Section	Facilitator activity	Notes
		(MOH) and the trend of diabetes in Malaysia	
5 min	T2DM	<ul style="list-style-type: none"> * The best strategy to fight in any battle is to understand the enemy. Let's explore the disease process to increase our understanding. * What does the term diabetes mean to you? <ul style="list-style-type: none"> * Prompt: disease? Symptoms? parts of body/organs? 	Provide information see Key learning point 1.2 . Review and reflects using OARS whenever suitable.
5 min	Normal food digestion	<ul style="list-style-type: none"> * Let's do some revision. * In groups please match the boxes to label the normal food digestion process in our body. 	Visual aid: Figure 1 .
5 min	Insulin	<ul style="list-style-type: none"> * Thank you for your participation. Shall we continue? * Explore: Anyone would like to share what is insulin? 	Visual aid: Figure 2 and Figure 3 . Provide information see Key learning point 1.3 .
5 min	T2DM and Insulin resistance	<ul style="list-style-type: none"> * We've discussed how our body digest food and how insulin works. * I've got some information what's happening to the insulin regulations in most people with T2DM. Is it okay we go over this? 	Visual aid: Figure 4 . Provide information see Key learning point 1.4 .
10 min	Complications	<ul style="list-style-type: none"> * So now let's have a look at the complications that you might face or already experience. * Please write down on the flipchart/whiteboard what might happen if you didn't control your blood sugar level? 	Write on flipchart. Provide information using visual aid: Figure 5 .
10 min	Eliciting change talk	<ul style="list-style-type: none"> * Write down your top reasons to reduce these complications. Refer workbook page 9. 	Review and reflects using OARS whenever suitable.
10 min	Goal setting	<ul style="list-style-type: none"> * We've discuss the reason for you to reduce the complications and to achieve this you need a good goal. * Evidence shows that goals may be more successful if you choose them rather being told. * Today we are going to discuss effective goal setting techniques by elaborating the important characteristics of a goal. Can anyone tell me what makes a good goal? 	Provide information see Key learning point 1.5 .
5 min	Group works	<ul style="list-style-type: none"> * In pairs, write a goal that will help you to reduce complications of T2DM. Write on the flipchart and present to group members. * Close session 	Write on flipchart. Review and reflects using OARS whenever suitable.

Key learning point 1.1



(NHMS 2015 compiled poster, 2015)

Key learning point 1.2

What is diabetes?

Diabetes is a complex metabolic characterised by hyperglycaemia (high blood glucose). When you have diabetes, your body is not able to properly use the food you eat for energy, particularly carbohydrates (sugary or starchy foods/drinks). This is because your pancreas is not making enough insulin or the insulin not working properly.

Key learning point 1.3

What is insulin?

Insulin is a hormone that is made by your pancreas. Your pancreas is a small gland located behind your stomach. As glucose enters the bloodstream, the pancreas releases a hormone called insulin. Insulin works to move the glucose out of bloodstream and into the cell where it provides the cell with energy. Because glucose moves out of the bloodstream your glucose levels stay within normal range.

Key learning point 1.4

T2DM and Insulin Resistance

Insulin resistance occurs when insulin attaches to the receptor sites on the cell, but the glucose channel remains closed, giving the sugar nowhere to go, or when fewer insulin receptor sites exist on the cell causing sugar to move into the cells at a slower rate. The resulting sugar remains in the bloodstream longer because insulin is less effective at open up glucose channels on the cells and the term used is hyperglycaemia. This causes the pancreas to make even more insulin. If this process is prolonged, it leads to the destruction (wearing out) of beta cells in pancreas that produce insulin.

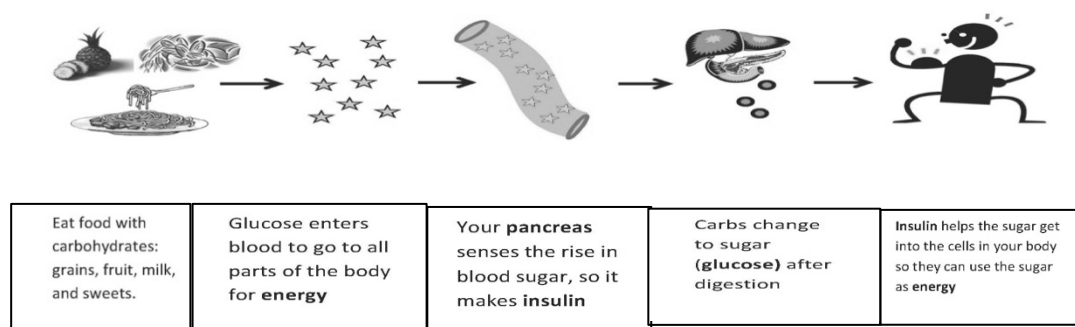
Key learning point 1.5

Self-management is an experiment and an individual do not have to completely ready to change in order to start the process. It is important to remember that effective goal must be specific, meaningful and realistic. It might be useful to share your goals with people around you and review them frequently to reduce the feeling of being alone and isolated.

Sample of a pledge or goal:

1. I will exercise (too general)
2. I will walk for 20 minutes for at least 3 days a week.
3. I will replace sugar with stevia sweetener.
4. I will take a 20 minutes' walk after dinner at least 3 days a week.

Figure 1

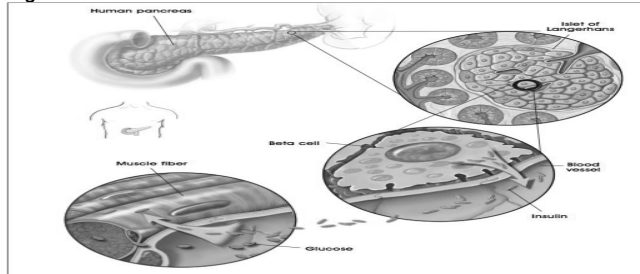


(How do we get energy from food?, 2013)

Normal food digestion

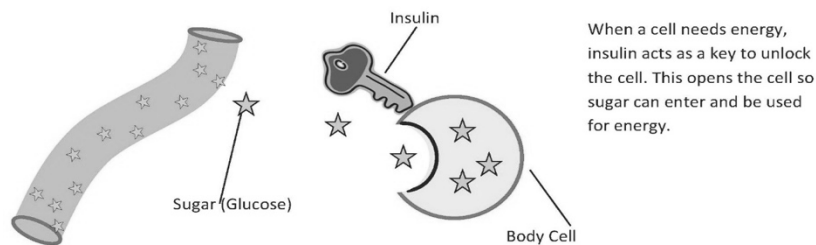
In the stomach and intestines food is broken down into its simplest forms by enzymes. Much of the food you eat is broken down into glucose and other simple sugars. After you digest your food, glucose travels through your blood stream. Your body's cells can now use it for energy. Glucose that is not used right away is stored for later use.

Figure 2



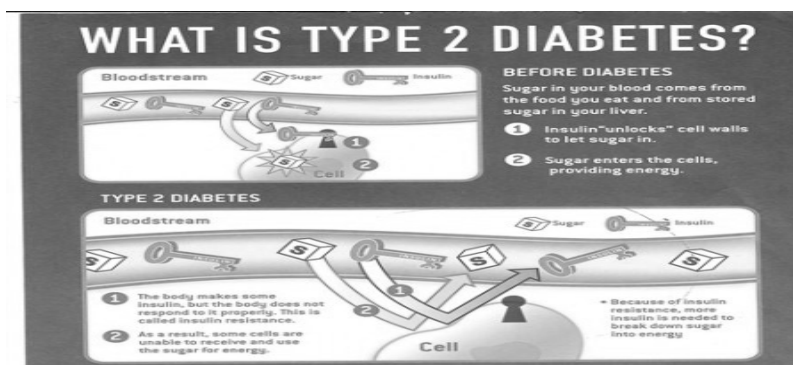
(Insulin and Glucagon are synthesized in pancreatic islet cell, 2000)

Figure 3



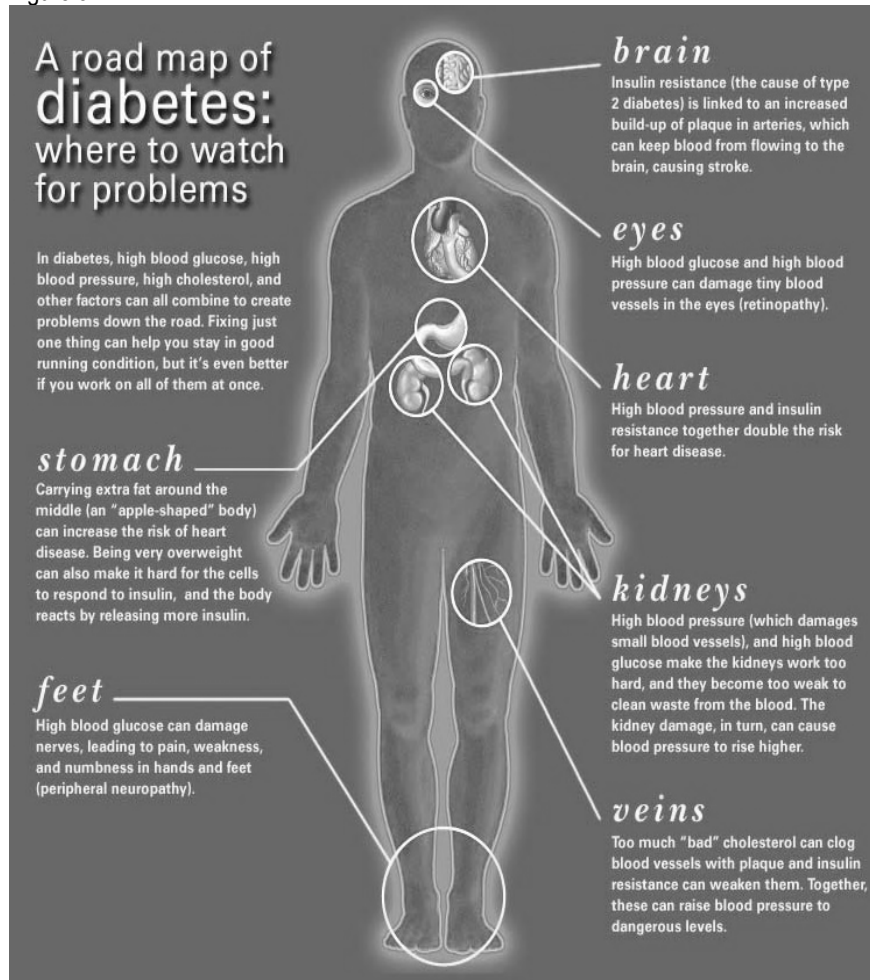
(How does insulin work?, 2013)

Figure 4



(What goes wrong in diabetes?, 2013)

Figure 5



(A road map of diabetes: Where to watch for problems?, no date)

Session 2: A sweet walk through time

Session : Session 2

Topic : A sweet walk through time

Time : 60 minutes

Theory : SCT

Aims

- Discuss the primary goal of diabetes self-management (blood sugar level).
- Elicit knowledge of diet for people with diabetes.
- Increase knowledge of healthy eating through understanding of low glycaemic index diet and healthy plate model.
- Increase self-efficacy by identification of barriers in meal planning and ways to overcome.

To conduct this session, you will need:

- MY DEUMI manual
- MY DEUMI workbook
- Post it notes
- Whiteboard or paper flip chart
- Glycaemic index quiz handouts

Components of theory (Session 2)

Theory	Components of theory	Specific aspects of the theory	Activities
Social Cognitive Theory (SCT)	Cognitive factors	Elicitation of knowledge	Introduction of primary goal of self-care
	Behavioural factors	Acquiring skills	Tools for healthy eating (healthy plate model, low glycaemic index diet)
		Self-efficacy	Identification of barriers in meal planning and ways to overcome. Goal or pledge settings.
	Environmental factors	Ability to change own environment	Identification of own ways towards behavioural modifications

Detailed lesson plan (Session 2)

Time allocation	Section	Facilitator activity	Notes
	Asking permission	* Elicit group agreement to continue session	
5 min	Primary goal of self-care	* Explore: What does the figure and the table mean to you?	Visual aid: Figure 5 and Table 7 . Review and reflect using OARS whenever suitable.
	Good news	* Is that okay for me to share some good news?	Provide information see Figure 6 , Figure 7 and Key learning point 2.1
15 min	Healthy eating	Let's start with healthy eating: * If thinking about diet, it is normal that we think off what to cut and eat less. Today, we'd like to introduce something different by thinking about what you need to eat or drink more of in order to control your blood sugar level. * Explore: What do you think that you need to eat and drink more? * prompt: types of food. * Refer workbook page 10-22 for notes	Write on flipchart. Review and reflects using OARS whenever suitable. Provide information see Key learning point 2.2 . Instruct participants to refer workbook for notes.
10 min	Low glycaemic index diet	Let's learn details about low glycaemic index diet through a simple quiz.	Distribute handout see Appendix 6: Glycaemic Index Quiz Instruct participants to refer workbook for notes.
10 min	Healthy plate model	* Elicit group agreement to continue * Explore: What method that can be used to help you to reduce your carbohydrate intake? * prompt: portion	Provide information see Appendix 7: Poster of Healthy Plate Model and Key learning point 2.3
10 min	Exploring perspectives	* This activity called "Good and Not So Good things". * Several of you are struggling with rice intake and how to cut portions and so you do not feel hungry. * It might be helpful to explore the things that you like about eating rice. Write on post it notes.	Collect all the post it notes. Review and reflects using OARS whenever suitable.

Time allocation	Section	Facilitator activity	Notes
		<ul style="list-style-type: none"> * There are some “not so good things” about consuming too much of rice too. What are those? Write on post it notes. * How does this lively discussion fit for you? 	Collect all the post it notes. Review and reflects using OARS whenever suitable.
5 min	Barriers	<ul style="list-style-type: none"> * Let’s have a look what might get in the way and how you can work around it? Write it in the workbook page 23. * Research suggests that by thinking and appreciating barriers and being prepared for obstacles in advance increases your success to change your lifestyle. 	Instruct participants to refer workbook. Review and reflects using OARS whenever suitable.
5 min	Conclusion	<ul style="list-style-type: none"> * Discuss in pairs, what is your goal regarding healthy eating? Write it in the workbook page 23. 	Instruct participants to refer workbook. Review and reflects using OARS whenever suitable.

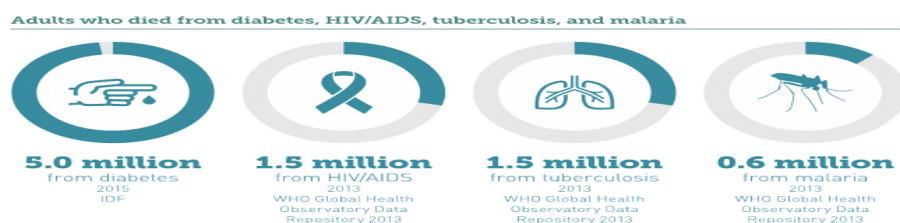
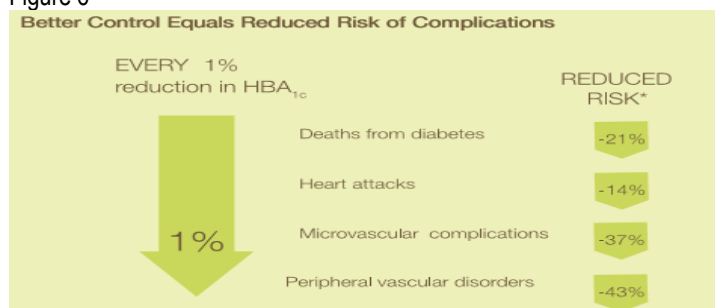
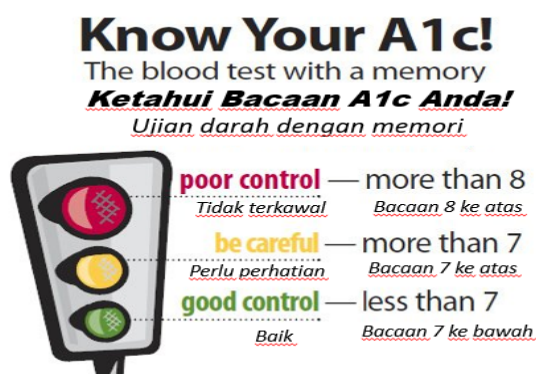


Figure 6



UKPDS study (Davis *et al.*, 1999)

Figure 7



Individualised A1c Targets and Patients' Profile		
Tight (6.0–6.5%)	6.6–7.0%	Less tight (7.1–8.0%)
<ul style="list-style-type: none"> Newly diagnosed Younger age Healthier (long life expectancy, no CVD complications) Low risk of hypoglycaemia 	<ul style="list-style-type: none"> All others 	<ul style="list-style-type: none"> Comorbidities (coronary disease, heart failure, renal failure, liver dysfunction) Short life expectancy Prone to hypoglycaemia

- Modified from Management of Hyperglycaemia in Type 2 Diabetes: A Patient-Centered Approach: A Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD), 2012. ^{50 (Level III)}

Adapted from (Ministry of Health Malaysia, 2015)

Key learning point 2.1

What is HbA1c?

The term HbA1c refers to glycated haemoglobin. It develops when haemoglobin, a protein within red blood cells that carries oxygen throughout your body, joins with glucose in the blood, becoming 'glycated'. By measuring glycated haemoglobin (HbA1c), clinicians are able to get an overall picture of what our average blood sugar levels have been over a period of weeks/months.

HbA1c (haemoglobin terglukosasi) merupakan ujian makmal yang mengemukakan purata glukosa darah untuk jangka masa merangkumi dua hingga tiga bulan. Secara khusus, ia mengukur bilangan molekul glukosa yang terikat kepada haemoglobin (sel darah merah). Individu yang normal mempunyai takat HbA1c kurang daripada 6 peratus. Ini bermakna kurang daripada 6 peratus molekul haemoglobin terikat secara kekal kepada glukosa.

Key learning point 2.2

i. Low glycaemic index diet

- Monitoring total carbohydrate (CHO) intake remains a key strategy in achieving glycaemic control.
- Both the amount and type of carbohydrates in food do affect blood glucose levels. The type of CHO is best described using the Glycaemic Index (GI) concept.
- Glycaemic index (GI) is a measure to classify type of CHO based on their effect on the blood glucose level. It is a ranking system that indicate how quickly CHO food raises blood glucose
- Food with high GI value raises blood glucose more than food with medium or low GI.
- Substituting high GI foods with lower GI foods at mealtime reduces postprandial blood glucose and modestly improve glycaemic control by reduction of A1c between 0.14% and 0.5%, provided the energy and total CHO intake are not excessive.

(Ministry of Health Malaysia, 2015)

ii. High fibre diet

- Good sources of fibre include wholegrains, vegetables, fruits, legumes, seeds and nuts
- Recommendation: 5-7 portions a day as below:
 - 4–5 portions of green leafy vegetables
 - 1–2 portions of fruits
 - 1 portions of legumes
 - 1 portions of wholegrains (wholemeal bread, oats, brown rice, chapatti)
- Benefits of adequate fibre intake:
 - Improves blood glucose
 - Lowers total and LDL cholesterol
 - Prevents constipation
 - Controls appetite by providing fullness
- Tips to increase fibre intake:
 - Choose whole grains products such as brown rice, wholemeal bread, oatmeal biscuits
 - Choose whole fruit instead of fruit juices
 - Include vegetables in every meal

(Malaysian Diabetes Educators Society, 2016)

iii. Carbohydrate (CHO) intake.

- Sources of preferred CHO include wholegrain cereals, fruit, low fat dairy products and legumes.
- The recommendation is 130mg/day equivalent to 8 to 9 exchange throughout the day.
- People with diabetes should limit intake of CHO from sugar sweetened drinks to reduce risk of weight gain and worsening of cardio metabolic risk. This includes drinks with white sugar, brown sugar, honey, gula melaka and condensed milk.
- Non-nutritive sweeteners may be used as a substitute for caloric sweeteners to reduce overall calorie and CHO intake. Example of non-nutritive sweeteners are aspartame (Equal). Bear in mind, this non-nutritive sweetener provides virtually no sense of satisfaction and may lead to extra calorie hunger and intake.

Key learning point 2.3

- Healthy plate method helps people with newly diagnosed T2DM get in control of their diet by changing the amount of food they eat. This is another way of eating smart for people with diabetes.
- The American Dietetic Association states that no single, universal diabetes diet plan works for all persons. As a general rule, a healthy diabetes diet plan should consist of properly balanced portions of carbohydrates, protein and fat to help stabilize blood glucose levels.
- Divide your plate into 4 sections:
 - Breakfast: a balance of half starchy foods, one-fourth fruit and one-fourth protein.
 - Lunch and dinner: fill $\frac{1}{2}$ the plate with non-starchy vegetables (such as: green leafy vegetables, beans, cabbage); $\frac{1}{4}$ should contain meat or other protein (fish, lean meat, skinless chicken); $\frac{1}{4}$ contains starch (such as rice, chapatti). On the side, you can have a serving of fruit.

Session 3: Diabetes medicine guide

Session : Session 3
 Topic : Diabetes medicine guide
 Time : 30 min
 Theory : Social Cognitive Theory
 Aims

- Introduce the different types of medications available to treat diabetes.
- Understand the mechanism and how these medicines affect our bodies and possible side effects.
- Increase confidence in consuming diabetes medicine

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Post it notes
- * Whiteboard or paper flip chart

Components of theory (Session 3)

Theory	Components of theory	Specific aspects of the theory	Activities
SCT	Cognitive factors	Elicitation of knowledge	Lively discussion: Available medicine for T2DM
		Attitudes	Lively discussion: The importance of discussion regarding T2DM medicine

Detailed lesson plan (Session 3)

Time allocation	Section	Facilitator activity	Notes
2 min	Myth or Fact	<ul style="list-style-type: none"> * If you have T2DM and your doctor says you need to start using insulin, it means you're failing to take care of your diabetes properly. * What is your opinion? 	Review and reflects using OARS whenever suitable. Provide information see Key learning point 3.2 .
10 min	Sharing moments	<ul style="list-style-type: none"> * Explore: In pairs, Write the name of medicine prescribed to you on the post it notes. 	Collect the post it notes and paste on empty flipchart.
	Classes of diabetes medicine	<ul style="list-style-type: none"> * In pairs, how do you think your medicine works and present to group members. 	Write on flipchart. Provide information see Key learning point 3.3
5 min	Information about diabetes medicine and possible side effects	<ul style="list-style-type: none"> * Offer information: May I share the information about type of oral diabetes medicine with you? Please refer to workbook page 24-25 for notes. 	Instruct participants to refer workbook for notes. Review and reflects using OARS whenever suitable.
10 min	Insulin	<ul style="list-style-type: none"> * From evidence, many people with or without diabetes are fearful of insulin. In some cases, initiation of insulin might benefit them in term of blood sugar control and may delays complications. * However, is not an easy thing to do every single day but thinking of the beneficial value might help to ease your feelings. * How does that sound to you? * Now, may I share to you how insulin works * Refer workbook page 25-26 for notes. 	Write answer on flipchart. Review and reflect the answers together. Instruct participants to refer workbook for notes.
3 min	Reflection	<ul style="list-style-type: none"> * Explore: Why do you think this session important. * Close session. 	Review and reflect the answers together

Key learning point 3.2

Fact: For most people, T2DM is a progressive disease. When first diagnosed, many people with T2DM can keep their blood glucose at a healthy level with oral medications. But over time, the body gradually produces less and less of its own insulin, and eventually oral medications may not be good enough to keep blood glucose levels normal. Using insulin to get blood glucose levels to a healthy level is a good thing, not a bad one.

Key learning point 3.3

- Classes of medication which lower blood glucose levels
 - Medications which reduce carbohydrate absorption from the gut
 - Medications which increase insulin secretion / production from the pancreas
 - Medications which improve insulin sensitivity
 - Medications which increase incretin levels
 - Medications which reduce glucose reabsorption in the kidney
 - Exogenous Insulin
- Some of these medications are available in combination tablets. Due to their different modes of action and side effects, people with diabetes who take these medications (and those who advise them) need to be aware of the importance of timing, dosage and other relevant factors.

Session 4: Keep calm and let's play!

Session : Session 4-Hands on session

Topic : Keep Calm and let's play!

Time : 120 minutes

Theory : SCT and TPB

Aims

- Elicit knowledge of requirement amount of fat, carbohydrate, sugar and salt per day
- Increase confidence in reading food labels
- Increase knowledge of fats content in several types of foods

Components of theory (Session 4)

Theory	Components of theory	Specific aspects of the theory	Activities
SCT	Behavioural factors	Acquiring skills	Food label reading, Sugar games, and Fat games. Pedometer as tools to increase physical activity
	Environmental factors	Access in community	Available resources for lifestyle modifications (label reader, pedometer)
TPB	Subjective norms about the behaviour	Opinion of referent others	Reflection sessions of the hands-on activities

Part 1 : Food Labels

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Table with label
- * Flipchart
- * Sample of food with nutrient information

Detailed lesson plan (Session 4: Part 1)

Time allocation	Section	Facilitator activity	Notes
60 min	Introduction	I would like to share with all of you the recommended amount of carbohydrate, sugar, fat, and salt per day. Is that okay?	Provide information see Key learning point 4.1.
	How to read labels?	Refer to handout given (How and when to read label?)	Distribute handout see Appendix 8: How to read food label. Provide information see Key learning point 4.2.
	Activity	Instruction: Please choose any of the food cartons on the table and read label using the label reader.	Display food carton on the table and distribute the label reader.
	Reflections	Explore: How this session would help you in your diabetes management?	Review and reflect using OARS where possible.

Part 2 : Sugar game

To conduct this session, you will need:

- * MY DEUMI manual
- * Table
- * Prepared tea spoon with sugar (1 teaspoon = 4 gram of sugar)
- * Sample of food and drink cartons with nutrient information

Detailed lesson plan (Session 4: Part 2)

Time allocation	Section	Facilitator activity	Notes
60 min	Group activity	Instruction: Choose any food carton on the front table and calculate the number of teaspoons of sugar contained in the chosen food (based on the food label). Instruction: Display the amount of sugar counted for the sample of food that you've chosen.	Prepare food cartons, table and spoon with sugar.
	Reflections	Explore: What have you learned from this session?	Review and reflect using OARS where possible.

Part 3 : Review pedometer

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Pedometer

Detailed lesson plan (Session 4: Part 3)

Time allocation	Section	Facilitator activity	Notes
Not applicable	Introduce pedometer	Explain how to use pedometer.	Provide information see Key learning point 4.5
	Individual assignment	Instruction: Please record your daily steps into your workbook from page 28. Next session, we'll collect how many steps you took in a day. This is just about seeing what you do normally and use it as baseline data that can be used to set an achievable target of daily steps in future. Close session.	Refer to baseline diary form in workbook page 28.

Key learning point 4.1

- i. CHO and sugar recommendations
 - a. Many ways to measure these such as using grams, exchange list, household or hand measures as long as it is practical for individuals to comprehend and follow.
 - b. One method is the exchange list and the recommendation is 130mg/day equivalent to 8 to 9 exchanges throughout the day.
 - c. Sucrose (table sugar) intake should be counted as part of total carbohydrate intake in a day. 1 CHO exchange is equivalent to 3 teaspoon of sugar or 2 table spoons of sweetened condensed milk so that you have only remaining 7 to 8 CHO exchanges for the day if you were to choose to include table sugar in your daily intake.
- ii. Salt or sodium intake recommendations
 - a. 5g or 1 teaspoon per day
 - b. This can be achieved by avoiding soya sauce, ketchup, oyster sauce, premixed cooking paste, monosodium glutamate, salt preserved foods and processed foods.
 - c. Also reducing the frequency of eating out and limiting salt in cooking (no added salt if using soya sauce or oyster sauce).
- iii. Reducing saturated fat
 - a. Can be found in cheese, yogurt, milk, cream, fatty cuts of meat, sausages, burger, pastry, cakes and biscuits.

Key learning point 4.2

When to use the label reader?

- At the supermarket, to check, compare and choose healthier options
- At home, to list foods which are unhealthy and to find healthier alternatives

Key learning point 4.3

The main objective for this activity is to create awareness regarding the amount of fat in usual foods such as yogurt, condensed milk, type of milk, part of meat and etc.

Key learning point 4.4

All of the sample foods have the same amount of fat. This activity is to create awareness that portion and size is very important in monitoring total of fat or other nutrients for people with diabetes.

Key learning point 4.5

You can begin using your pedometer after you:

- Clip it onto your waist (use the extra safety clip so it doesn't fall off).
- Your pedometer must be closed in order for it to accurately count your steps.
- When you wake up every morning, remember to reset your steps by holding down the RESET button.

Session 5: Let's move! to stay healthy and lose weight

Session : Session 5
Topic : Let's move! to stay healthy and lose weight
Time : 30 min
Theory : SCT and TPB
Aims

- Invite reflections from last session
- Elicit knowledge about physical activity
- Provide information regarding walking and sedentary lifestyle
- Determine the activities that are good for diabetes management
- Determine how much activity they should do

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Whiteboard or paper flip chart

Components of theory (Session 5)

Theory	Components of theory	Specific aspects of the theory	Activities
SCT	Behavioural factors	Self-efficacy	Reflections from previous sessions
	Environmental factors	Influence on others	Sharing experiences from previous sessions outcome
		Acquiring skills	Introduction of walking activity as part of exercise
TPB	Attitudes toward the behaviour	Beliefs about behaviours	Lively discussion: Benefits of walking

Detailed lesson plan (Session 5)

Time allocation	Section	Facilitator activity	Notes
10 min	Reviews	<ul style="list-style-type: none">* Explore: Have you any thoughts or reflections from previous sessions?* In pairs discuss: (i) one thing you achieved up to this session (ii) anything you have learnt/ would change for coming months/ what worked/what did not work.	Give positive feedback to the group members who did well with their goals. Encourage members who had a hard time with their goals to improve self-management skills.

Time allocation	Section	Facilitator activity	Notes
		* Please present to the group members	Review and reflect using OARS where possible.
5 min	Information about physical activity	* Explore: What do you do to be physically active? * I appreciate the efforts you've made	Review and reflects using OARS whenever suitable. Provide information see Key learning point 5.1 .
	Building confidence	* How many of you have lost weight before? * How did you feel (name) when you lost weight? * Reflection: What would it be like if you strengthen your commitment by combining all of these experiences together	Write answer on empty flipchart. Review and reflect using OARS where possible.
5 min	Introduce walking as part of physical activity	* Explore: How much exercise do you think you need each day to improve your health? * Explore: What is your thought of the recommendation for physical activity and the poster?	Provide information see Key learning point 5.2 Visual aid: Appendix 9: Poster of recommendations number of steps a day
5 min	Eliciting change talk	* Explore: In pairs, discuss why you think we should choose walking as a form of exercise?	Provide information see Key learning point 5.3
5 min	Barriers to increase physical activity	* Please refer to the workbook page 30 and let's have a look what might get in the way and how you can work around it? * Close session.	Instruct participants to refer workbook.

Key learning point 5.1

Increased physical activity helps to:

1. Improve glycaemic control (improves insulin action)
2. Assist weight management
3. Reduce risk of CVD

(Ministry of Health Malaysia, 2015)

Key learning point 5.2

General recommendations of physical activity:

1. Exercise 5 days a week for a duration of 150 minutes/week (moderate intensity aerobic physical activity) with no more than 2 consecutive days without physical activity
 - a. moderate exercise is when your breathing is slightly heavy; you can feel your pulse and warmer. The good news is that it doesn't have to be 30 minutes in one go.
2. Overweight and obese to increase to 60-90 minutes per day for long term weight loss

(Ministry of Health Malaysia, 2015)

Key learning point 5.3

Why we should choose walking as form of exercise:

1. No special equipment
2. Part of everyday routine
3. It can be done with families and friends
4. It's free (saves money)
5. Easily adapted
6. Maximum gain with minimum effort

Session 6: Keep calm and keep walking!

Session : Session 6
 Topic : Keep calm and keep walking!
 Time : 30 min
 Theory : SCT and TPB
 Aims

- Develop skills that help to increase physical activity
- Increase confidence to increase physical activity

To conduct this session, you will need:

- MY DEUMI manual
- MY DEUMI workbook
- Pedometer

Components of theory (Session 6)

Theory	Components of theory	Specific aspects of the theory	Activities
SCT	Cognitive factors	Elicitation of knowledge	Introduction of pedometer
	Behavioural factors	Practice	Workbook for progress monitoring
		Acquiring skill	Using pedometer for walking activities to measure progress
		Self-efficacy	Identification of barriers and ways to overcome
	Environmental factors	Access in community	Walking activities as easy free access
TPB	Subjective norms about the behaviour	Motivation to comply	Reflection session with group members after simple walking activity
	Attitudes toward the behaviour	Evaluation of the behaviour	Reflections on activities to burn calories

Detailed lesson plan (session 6)

Time allocation	Section	Facilitator activity	Notes
10 min	Introduction	* Let's start: What is your thought of these activities to burn calories?	Visual aid: Figure 8 , Figure 9 and Figure 10 Review and reflect using OARS where possible.
	Broadening perspectives (A typical day)	* Can we spend the next 5 minutes going through a day from beginning to end? Please complete the worksheet in the workbook page 31 that elicits your typical morning, afternoon, evening and night time activities.	Instruct participants to refer workbook.
	Opportunities for more routine movement	* Explore: Using the worksheet, where there are opportunities to increase your number of steps? Discuss and write in your workbook page	Instruct participants to refer to workbook.
5 min	Into action	* Explore: How to start? * Prompt: tools, types of activity	Provide information see Key learning point 6.1
	Average steps per day	Explore: For those who recorded their steps from previous session, how did you find it?	Review and reflect using OARS where possible.

10 min	Activity	Instruction: Let's put on our pedometer and do this simple activity to understand the intensity of physical activity.	Provide information see Key learning point 6.2
		Reflections session: * How many calories have you burnt while doing this exercise? * How do you feel about this?	Review and reflect using OARS where possible.
5 min	Goal setting	* Now, have some time to think about the number of steps that you would like to target for coming week. Write in the workbook page 32.	Instruct participants to refer to workbook.
	Individual assignment	* Instruction: Please note down your daily steps measured using your pedometer daily. This will help you see your progression. Refer to the diary section.	Instruct participants to refer to workbook to fill the number of steps daily.

Figure 8

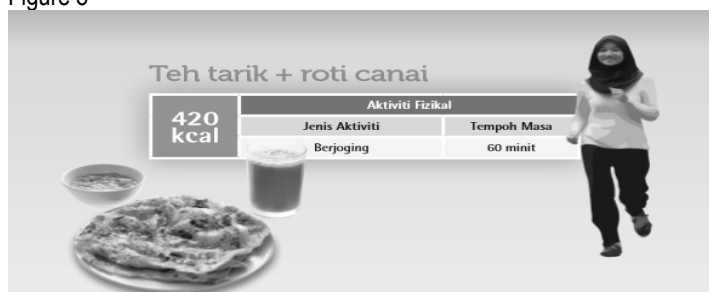


Figure 9



Figure 10



Key learning point 6.1

- Research shows that walking 10,000 steps a day will significantly improve your health.
- Average person walks 3000 to 4000 steps per day. 1000 step is equivalent of around 10 minutes of brisk walking.

Session 7: Diabetes foot

Session : Session 7
 Topic : Diabetic foot
 Time : 30 min
 Theory : SCT and TPB
 Aims

- Discuss the risk and complications of diabetic neuropathy
- Conduct foot ulcer risk assessment
- Provide basic information and guidelines for the prevention of foot ulcers
- Increase awareness regarding importance of foot care for people with diabetes

To conduct this session, you will need:

- MY DEUMI manual
- MY DEUMI workbook
- Semmes-Weinstein monofilament
- Emollient cream
- Figure 9
- Diabetic foot ulcer risk assessment form

Components of theory (Session 7)

Theory	Components of theory	Specific aspects of the theory	Activities
SCT	Cognitive factors	Elicitation of knowledge	Information on diabetic foot ulcers
		Attitudes (elicitation of beliefs)	Reflections on diabetic foot ulcer complications using visual aid
	Behavioural factors	Acquiring skills	Hands-on activity: foot care
	Environmental factors	Ability to change own environment	Identification of own ways towards behavioural modification
TPB	Subjective norms about the behaviour	Opinion of referent others and motivation to comply	Reflections from group activity: foot care
	Attitudes toward the behaviour	Evaluation of the behaviour	Lively discussion: How to reduce the risk of diabetic foot ulcer

Detailed lesson plan (Session 7)

Time allocation	Section	Facilitator activity	Notes
5 min	Review	* At this point, do you have any questions/ concerns about the programme	Review and reflect using OARS where possible.
	Introduction	* Explore: What are your thoughts of this picture?	Visual aid: Figure 11 Provide information see Key learning point 7.1
	Reduce the risk	* Explore: What you can do to reduce your risk?	Provide information see Key learning point 7.2
10 min	Risk assessment	* Let's assess your risk * Instruction: I will assess each of you and share the result with you.	Assess participant's risk using Appendix 10: Diabetic Foot Ulcer Risk Assessment Provide information see Key learning point 7.3
10 min	Activity (Daily foot care)	* First, please check your feet using mirror. Look for redness, blisters, soggy skin, cracks, swelling, corns and calluses or ingrown toenails. Refer to workbook page 34-35 for notes.	Instruct participants to refer to workbook for notes.
		* Second, make sure your footwear fits well. Let's practice! Evaluate your	Collect the post it notes and paste on flipchart

	footwear's. Does it fit well, support the foot and not too tight. Give your reflections and write it on post it notes.	Review and reflect the answers together.
	* Third, clean your feet every day, dry well (do not soak) and apply emollient cream if skin is dry. Please try to apply the cream provided.	Prepare the emollient cream.
	* Explore: How do you feel?	Review and reflect using OARS where possible.
* Reflection	* Explore: What do you think of this session?	Review and reflect using OARS where possible.
	* Close session	

Figure 11



Adapted from (*Ischaemic necrotic toe*, no date)

Key learning point 7.1

High blood glucose from diabetes causes two problems that can affect your feet:

- Nerve damage. One problem is damage to nerves in your legs and feet. With damaged nerves, you might not feel pain, heat, or cold in your legs and feet. A sore or cut on your foot may get worse because you do not know it is there. This lack of feeling is caused by nerve damage, also called diabetic neuropathy. Nerve damage can lead to a sore or an infection.
- Poor blood circulation. The second problem happens when not enough blood flows to your legs and feet because diabetes causes blood vessels of the feet and leg to narrow and harden. Poor blood flow makes it hard for a sore or infection to heal. This problem is called peripheral vascular disease, also called PVD. Smoking when you have diabetes makes blood flow problems much worse.

Key learning point 7.2

Protect your feet by following action:

1. Stop smoking
2. Improve blood glucose level
3. Daily inspection- ulcer, deformities, calluses
4. Always wear shoes
5. Keep clean and dry
6. Safety first when using nail clippers

Key learning point 7.3

Explain the level of risk and the intervention guide:

Lower Risk	<ol style="list-style-type: none"> 1. Explain risk for foot complications related to diabetes. 2. Teach basic foot care practices 3. Reinforce the benefits of annual foot examination
Higher Risk	<ol style="list-style-type: none"> 4. Explain risk for foot complications related to diabetes. 5. Teach basic foot care practices 6. Reinforce the benefits of regular foot examination (every 3 to 6 months)

Session 8: Dealing with diabetes

Session : Session 8
 Topic : Dealing with diabetes
 Time : 60 minutes
 Theory : SCT and TPB

Aims

- Express feelings about having diabetes
- Understand the physical response to stress
- Provide ways to cope with the emotional impact and to uphold a good quality of life

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Dice
- * Stationery
- * Paper
- * Rewards (gift)

Components of theory (Session 8)

Theory	Components of theory	Specific aspects of the theory	Activities
SCT	Cognitive factors	Attitude (elicitation of beliefs)	Lively discussion: exploration of the importance of stress management
	Behavioural factors	Acquiring skills	Hands-on activity: deep breathing exercise
	Environmental factors	Influence on others	Lively discussion: methods to reduce anxiety in daily events
TPB	Subjective norms about the behaviour	Opinion of referent others	Lively discussion: reflection session of the activity (come on six game)

Detailed lesson plan (Session 8)

Time allocation	Section	Facilitator activity	Notes
15 min	Asking permission	<ul style="list-style-type: none"> * Elicit agreement to continue the programme * Explore: Answer questions in the workbook page 37 	Instruct participants to refer to workbook. Provide information see Key Learning point 8.1.
	Realizing your potential	<ul style="list-style-type: none"> * Reflection: Identify your feelings may help you find your way. Looking for help is not a failure. It takes a strong person to recognise help is needed. 	
5 min	Stress	<ul style="list-style-type: none"> * Explore: Why is that important for people with diabetes to manage their stress. Discuss in pairs and present your answer. 	Provide information see Key Learning point 8.2.
20 min	Activity	Let's play	Instruction see Appendix 12: Come on Six (by Tom Jackson's) .
	Reflection	<ul style="list-style-type: none"> * How easy was it for you to roll a six? * When the activity began, what was the level of excitement in your group? * How can we compare this activity to stress in our lives? 	Write on flipchart. Review and reflect using OARS where possible.
10 min	Stress level assessment	Let's measure <ul style="list-style-type: none"> * Instruction: Answer the Depression, Anxiety, Stress Scale (DASS 21) test in your workbook page 38-39. 	Instruct participants to refer to workbook.

		* Who wants to share your feeling after taken this test?	Review and reflect using OARS where possible.
10	Activity	* Well done, you've expressed your emotions. When you're accepting and open about having diabetes, you'll find that you're not alone in your situation and get control of it. * Explore: What are some of the positive things you are comfortable doing to reduce your anxiety or stress levels? Write it on post it notes	Collect and paste the post it notes on the empty flipchart Provide information see Key Learning points 8.3
		Now, let's relax ourselves by referring to the deep breathing techniques in the workbook page 40. Close session.	Provide information see Appendix 13: Deep breathing exercise

Key Learning point 8.1

The emotions below can be experienced by anyone. Identification and acceptance of these emotions helps people with diabetes to adjust to the condition.

i. Denial:

Initial denial is important to prevent us from being emotionally overwhelmed. "I can't be sick"; "Why me? I don't deserve this". It becomes unhealthy when it interferes with the ability to take care of your diabetes.

ii. Sad:

This is a normal response because it requires changes in lifestyle to control the disease. If it lasts for two or more weeks it may be a sign of depression and you may need to tell someone and get help. It reduces the motivation and energy for self-care.

iii. Fear:

It is common to feel loss of control over your body. "What is going to happen to me?"; "Will I eventually lose my limbs?". It can also be healthy to motivate you to learn more about diabetes management but it also can lead to hopelessness. Family members might be overprotective and restrict activities.

iv. Anger:

This can be unhealthy if it is too strong and direct to a person. Anger to self may lead to reluctance to care or control the diabetes. Remember that as long you're angry, you are not in a problem solving mode. Diabetes requires your focus and attention.

v. Guilt:

We feel guilty as we believe that we are responsible for something bad happening. "If I hadn't eaten so much, I wouldn't have diabetes."; "I really deserve this after what I've done". Too much guilt makes us feel like a failure and can lead to depression.

vi. Acceptance:

Time will heal the pain and sadness but sometimes it may not. You must work through this until a level of acceptance is reached.

Key Learning point 8.2

The body reacts to stress in various ways:

1. Heart rate increases
2. Blood pressure increases
3. Breathing becomes rapid and shallow
4. Muscles get tense
5. Blood sugar may rise

Key Learning points 8.3

1. Bertenang (Keep calm)
2. Bernafas dengan dalam (Deep breathing)
3. Berkata: relaks la! (Say: please relax!)
4. Beribadat (Pray)
5. Bercakap dengan seseorang (Talk to someone)
6. Beurut (Body massage)
7. Berehat dan mendengar muzik (Relax and listen to music)
8. Beriadah (Sports)
9. Bersenam (Exercise)
10. Berfikiran positif (Positive thinking)

Session 9: Complementary and alternative medicine (CAM)-Herbal medicine

Session : Session 9
 Topic : Complementary and Alternative medicine (CAM)-Herbal medicine
 Time : 30 min
 Theory : SCT and TPB
 Aims

- Understand the term of complementary medicine or alternative medicine and available treatment.
- Elicit the importance of herbal medicine in self-management.
- Increase awareness of effects of abusive use of herbal medicine to people with diabetes

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Post it notes
- * Whiteboard or paper flip chart

Components of theory (Session 9)

Theory	Components of theory	Specific aspects of the theory	Activities
SCT	Cognitive factors	Attitude (Elicitation of beliefs)	Lively discussion: Usage of CAM among members
	Environmental factors	Access in community (Available resources)	Lively discussion: Popular natural herbs with evidence base and its possible side effects
TPB	Subjective norms about the behaviour	Opinion of referent others	Lively discussion: perceptions regarding effectiveness of herbal medicine
	Attitudes toward the behaviour	Beliefs about behaviour	Lively discussion: Usage of CAM among members

Detailed lesson plan (Session 9)

Time allocation	Section	Facilitator activity	Notes
5 min	Asking permission	* Elicit agreement to continue the session.	
		* Explore: How many of you are interested in complimentary medicine or to be specific herbal medicine?	Assess the number of hands Provide information see Key Learning point 9.1
5 min	Exploring values	Explore: Why did you choose to include CAM in your diabetes management? Write it on the post-it note.	Collect the post it notes and paste on flipchart. Review and reflect using OARS where possible.
10 min	Exploring values	* Explore: How do you think CAM helps in your diabetes management? * Reflection sessions	Review and reflect using OARS where possible.
5 min	Broadening perspectives	* Instruction: In pairs, list any CAM that you've been using and in what way it works. Share your discussion with all. * Please refer workbook page 41 for notes.	Provide information see Key Learning point 9.2 and Key learning point 9.3
5 min	Reflection	* What is your thought towards CAM usage in diabetes management after this session? * Close session	

Key Learning point 9.1

Definition

Traditional medicine has a long history. It is the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses. The terms complementary/alternative/non-conventional medicine are used interchangeably with traditional medicine in some countries. (World Health Organisation, 2000)

Available alternative treatments:

1. Medicinal herbs: most popular in Malaysia about 70% of people T2DM choose to include herbal medicine as part of treatment (Ministry of Health Malaysia, 2015)
2. Nutritional supplementation
3. Acupuncture
4. Oxygen therapy

Key Learning point 9.2

Herbs used for the treatment of T2DM in Malaysia.

Medicinal Herb	English or Local name	How it works	Side effects
Ginseng species (Asian and American)	Ginseng	* May slow digestion and reduce rate of carbohydrate absorption	❖ Nervousness and excitation ❖ Massive overdose may lead to hypertension, insomnia or oedema
Momordica charantia (Asia, Africa and South America)	Bitter guard/melon Peria katak	* More potent than hypoglycaemic agent * Insulin-like protein * Inhibit gluconeogenesis (process of producing glucose from non-CHO sources e.g fat and occurs mainly in liver)	❖ Hepatic inflammation and testicular lesions in dogs after long term usage
Trigonella foenum graceum (India)	Fenugreek Halba	* Reduced fasting and post-prandial glucose level	❖ Unknown
Orthosiphon stamineus	Java tea Misai kucing	* In rat-experiment: it increased insulin secretion by pancreas	❖ Unknown
Andrographis paniculata	Hempedu bumi	* Methanol extract reduces glucose absorption in blood * In rat experiment: increased insulin efficiency	❖ Headache, diarrhoea and lethargy
Rebaudiana stevia	Stevia Daun manis	* Sweet plant with no calories * Human studies increase in glucose tolerance and decrease in blood glucose level * Stimulates beta cells to release insulin * Reduces the craving for sweet and fatty foods by providing satisfaction	❖ Unknown

(Dey, Attele and Yuan, 2002; *Pengubatan alternatif komplementari bagi diabetes mellitus*, 2010; Peter and Sabina, 2016)

Key learning point 9.3

Take home message:

- i. The success of CAM can be difficult to measure. If medical treatment for diabetes is delayed it may result harm to the individual with T2DM
- ii. Most herbal medicines are approved as supplements due to no available clinical trials and most studies are performed on animals.
- iii. Need to be aware of potential side effects and drug interactions.
- iv. These therapies may financially benefit those who developed, promoted or approved them.
- v. Openly discuss with your doctors if you choose to consume this herbal medicine to monitor drug interactions.

Session 10: Relapse prevention

Session : Session 10
 Topic : Relapse prevention
 Time : 60 min
 Theory : SCT and TPB

Aims : By the end of this session, group members will be able to:

1. Develop self-efficacy and increase their self-confidence for lifestyle modification
2. Recognise what turns a lapse into a relapse
3. Reflect on individual hotspots and ways to handle it

To conduct this session, you will need:

- * MY DEUMI manual
- * MY DEUMI workbook
- * Container for group activity
- * Whiteboard or paper flip chart

Components of theory (Session 10)

Theory	Components of theory	Specific aspects of the theory	Activities
Social Learning Theory (SCT)	Cognitive factors	Elicitation of knowledge	Lively discussion: Understanding lapses
	Behavioural factors	Self-efficacy	Group work: Identification of barriers towards lifestyle modification. Reflections of case studies

Detailed lesson plan (Session 10)

Time allocation	Section	Facilitator activity	Notes
	Asking permission	Elicit agreement to continue the session.	
	Broadening perspectives	<ul style="list-style-type: none"> * Now, let's read a story. Please refer to your workbook on page 42. * Previous activity helps you to plan ways to deal with setbacks, is it possible to avoid them? * In pairs, discuss: <ol style="list-style-type: none"> What's the difference between lapses and relapse? What turns a lapse into relapse? * Please refer workbook page 43-44 for notes. 	Write on flipchart. Review and reflect the answers together. Provide information see Key Learning point 10.1
15 min	Inspiration and motivation (activity)	<ul style="list-style-type: none"> * It is important to focus on things about you that make you amazing, in order to increase your confidence. It's very powerful to hear how others view us. * This exercise, where each of you writes down something nice about every other person in the room might help us to boost our confidence. Please write each member's name and one strength that they possess. It could be something you've noticed in group or something you know from outside of group. Do not put your name on the paper. * Please put your comments in the container in the middle room. 	Prepare a container and read loud the answers. Review and reflect using OARS where possible. Instruct participants to refer to the workbook for the inspiring stories.

Time allocation	Section	Facilitator activity	Notes
		<ul style="list-style-type: none"> * Write down the positive qualities that your peers mention in the workbook page 44. Use this list to affirm yourself in future. * Let's read an inspiring story in the workbook page 45. 	
10 min	Confidence ruler	<ul style="list-style-type: none"> * Refer to worksheet in the workbook page 46. 1. Think of a current problem that affects your blood sugar control. 2. Then go to the ruler and round the number of the scale how important to solve this problem. 3. How confident you feel to do it. 	Reflect their answer by asking what makes it X and not zero. (Eliciting change talk using OARS.
15 min	Reflection	<ul style="list-style-type: none"> * What would need to occur for you to move one scale point higher? * Close session 	Generating a discussion about additional skills, supports or resources that might increase their confidence to change.

Key Learning point 10.1

Understanding how lapse become relapses

How a lapse turns into a relapse! (Bagaimana ponteng/terlepas melaksanakan matlamat iaitu perubahan gaya hidup boleh membawa anda kembali ke tabiat lama)



Avoiding a Relapse (Bagaimana mengelak kembali ke tabiat lama).



Things to do:

- ❖ Don't turn a lapse into a relapse by keeping it to yourself. Share your feelings with someone you trust.
- ❖ Get back on track by setting very small goals that are easy to accomplish. Build up gradually.
- ❖ Get a positive vibe around you.

Session 11: Closing

Session : Session 11
 Topic : Closing
 Time : 30 min
 Theory : Not applicable
 Aims

1. Review what has been covered in session 1 to 10
2. Reflect what has been gained throughout the programme
3. Formula individual goal/s

To conduct this session, you will need:

- MY DEUMI workbook
- list of contact numbers for whatsapp application
- list of email for facebook application

Detailed lesson plan (Session 11)

Time allocation	Section	Facilitator activity	Notes
15 min	Asking permission	* Elicit agreement to continue the session.	
	Review	* It's time to wrap up and reflect on what you've gained throughout this programme.	Review and reflect using OARS where suitable.
10 min	Evaluation	* In pairs, please discuss: <ul style="list-style-type: none"> ▪ What did you enjoy the most about MY DEUMI? ▪ What will you miss? ▪ Write it on post it notes and stick on the flipchart. 	To inform regarding whatsapp group and facebook group forum will be available for further discussion
	Individual assignment	* Please record your daily steps a day's log in the workbook along with other blood results, weight and waist circumference information from page 47-55.	
5 min	Closing	* Looking forward to the follow up session in 3 months to review your achievements! * Wishing you all the very best for future healthier lives! * Thank you.	Remind of telephone follow up at 2 nd month after this session.

***** Thank You *****

Appendix 1: Programme outline

Duration (minutes)	Day 1 (5 hours)
30	Introduction 1: Are you ready? Pengenalan 1: Adakah anda bersedia?
30	Introduction 2: Towards an effective self-management. Pengenalan 2: Kearah penjagaan sendiri yang efektif.
60	Session 1: What is diabetes? Sesi 1: Apa itu diabetes?
	Take five Rehat.
60	Session 2: Eating in balance: A sweet walk through time. Sesi 2: Pemakanan seimbang: Perjalanan manis sepanjang masa.
30	Session 3: Diabetes Medicine Sesi 3: Panduan ubatan diabetes.
	Break Rehat
1 hour	BREAK
120	Session 4: Keep calm and Let's play. Sesi 4: Latihan dalam kumpulan. Food labels. (label makanan). Sugar game. (berapa banyak gula dalam makanan anda). Fat game. (berapa jumlah lemak dalam makanan anda).
Duration (minutes)	Day 2 (5 hours)
30	Session 5: Keep moving, stay healthy and lose weight. Sesi 5: Terus aktif untuk kekal sihat dan turunkan berat badan anda.
30	Session 6: Move it! Let's play. Sesi 6: Mari bermain!
30	Session 7: Diabetes foot. Sesi 7: Penjagaan kaki pesakit diabetes.
	Take five. Rehat.
60	Session 8: Living and coping with diabetes. Sesi 8: Hadapi diabetes dengan tenang.
30	Session 9: Complementary and alternative medicine. Sesi 9: Ubatan tradisional: Apa pilihan anda.
	Break. Rehat.
60	Session 10: Relapse prevention Sesi 10: Gagal untuk berubah? Jangan putus asa masih belum terlambat.
60	Session 11: Yes, I can do it! Sesi 11: Saya boleh!




Appendix 2: Bingo ice-breaking game

Coffee lover	Owens a cat	Born in _____	Likes to clean
Favourite colour is red	Has 2 children	Born in _____	Enjoy fishing
Tea lover	Is left handed	Like spicy food	Has brown eyes
Favourite colour is blue	Born in _____	Is eldest in the family	Enjoys gardening
Ride motorcycle	Has been hospitalised before	Like to watch drama (TV)	Drives a car

Appendix 3: "Are you ready?" checklist

Making lifestyle changes can be very challenging but beneficial to your health

• Are You Ready?

 <p>Balance your plate</p>	 <p>Choose to move</p>	 <p>Kick the habit</p>
Please check and tick each statement that is true		
Eat fruits and vegetables and reasonable portions of high fibre and lean protein foods.	30 minutes of physical activity most days of the week	No tobacco products of any kind
<input type="checkbox"/> I'm currently eating a healthy diet.	<input type="checkbox"/> I already do	<input type="checkbox"/> I am not using tobacco products of any kind
<input type="checkbox"/> I'm ready to make healthy changes	<input type="checkbox"/> I'm ready to start increasing my physical activity	<input type="checkbox"/> I'm ready to try quitting using tobacco products
<input type="checkbox"/> I'm thinking about trying to make healthy changes	<input type="checkbox"/> I'm thinking about becoming more physically active	<input type="checkbox"/> I'm thinking about trying to quit using tobacco products
<input type="checkbox"/> I'm not ready to make healthy changes to my diet	<input type="checkbox"/> I'm not active and am thinking about becoming physically active	<input type="checkbox"/> I'm not ready to quit using tobacco

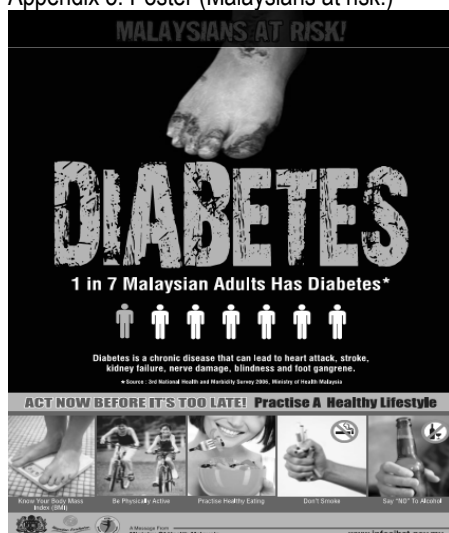
Adapted from (Robert C. Byrd, 2008)

Appendix 4: Diabetes knowledge question

Please tick (/) your answer: Sila tandakan(/) jawapan anda:				
Item	Questions / Soalan	Yes Ya	No Tidak	I don't know Saya tidak tahu
1	Eating too much sugar and other sweet foods is a cause of diabetes. Makan gula berlebihan dan makanan yang manis adalah punca diabetes.		/	
2	The usual cause of diabetes is lack of effective insulin in the body. Punca diabetes adalah disebabkan ketidakupayaan insulin berfungsi dengan efektif dalam tubuh badan.	/		
3	Diabetes is caused by failure of the kidneys to keep sugar out of the urine. Diabetes adalah disebabkan oleh kegagalan buah pinggang menyingkirkan gula melalui air kencing.		/	
4	Kidneys produce insulin. Buah pinggang menghasilkan insulin.		/	
5	In untreated diabetes, the amount of sugar in the blood usually increases. Kebiasaannya, kadar gula semakin meningkat dalam salur darah pesakit diabetes yang tidak dirawat.	/		
6	If I am diabetic, my children have a higher chance of being diabetic. Jika saya menghidap diabetes, anak saya mempunyai kebarangkalian yang tinggi untuk menghidap penyakit ini.	/		
7	Diabetes can be cured. Diabetes boleh dirawat.		/	
8	A fasting blood sugar level of 12mmol/L is too high. Bacaan gula dalam darah semasa berpuasa sebanyak 12.0 mms l/L adalah sangat tinggi.	/		
9	The best way to check my diabetes is by testing my urine. Kaedah terbaik untuk memeriksa diabetes adalah melalui ujian air kencing.		/	
10	Regular exercise will increase the need for insulin or other diabetic medication. Senaman berkala meningkatkan keperluan insulin atau ubatan lain diabetes.		/	
11	There are two types of diabetes: type 1 (insulin-dependent) and type 2 (non-insulin dependent) Terdapat dua jenis diabetes: jenis 1(bergantung kepada insulin) dan jenis 2 (tidak bergantung kepada insulin).	/		
12	An insulin reaction is caused by too much food. Tindakan insulin adalah disebabkan oleh pengambilan makanan yang banyak.		/	
13	Medication is more important than diet and exercise to control my diabetes. Ubatan adalah lebih penting berbanding pengawalan makanan (diet) dan senaman untuk mengawal diabetes saya.		/	
14	Diabetes often causes poor circulation. Diabetes selalunya mengakibatkan gangguan pada pengaliran darah dalam tubuh.	/		
15	Cuts and abrasions on diabetics heal more slowly.	/		

	Luka dan lelasan pesakit diabetes akan sembuh pada kadar yang perlahan.			
16	Diabetics should take extra care when cutting their toenails. Pesakit diabetes perlu berhati-hati semasa memotong kuku jari kaki.	/		
17	A person with diabetes should cleanse a cut with iodine and alcohol. Seseorang yang menghidap diabetes seharusnya mencuci luka menggunakan iodine dan alcohol.		/	
18	The way I prepare my food is as important as the food I eat. Cara penyediaan makanan adalah sama penting dengan jenis makanan yang saya makan.	/		
19	Diabetes can damage my kidneys. Diabetes boleh merosakkan buah pinggang.	/		
20	Diabetes can cause loss of feeling in my hands, fingers, and feet. Diabetes boleh mengurangkan deria rasa pada tangan, jari dan kaki saya.	/		
21	Shaking and sweating are signs of high blood sugar. Berpeluh serta menggigil merupakan tanda-tanda kandungan gula yang tinggi dalam darah.		/	
22	Frequent urination and thirst are signs of low blood sugar. Kerap kencing dan dahaga adalah tanda-tanda kandungan gula yang rendah dalam darah.		/	
23	Tight elastic hose or socks are not bad for diabetics. Stokin kaki elastik yang ketat elok untuk pesakit diabetes.		/	
24	A diabetic diet consists mostly of special food. Diet pesakit diabetes biasanya terdiri daripada makanan khas.		/	

Appendix 5: Poster (Malaysians at risk!)



(Ministry of Health Malaysia, 2011)

Appendix 6: Glycaemic Index (GI) Quiz (Kuiz Indeks Glisemik(GI))

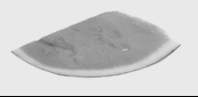

Question 1

How much white rice do you eat in one meal? (Barapa banyak nasi yang anda ambil pada setiap waktu makan?)

- 1 bowl (1 mangkuk)
- 2 bowl (2 mangkuk)
- 3 bowl (3 mangkuk)
- 4 bowl (4 mangkuk)

Question 2





Which one has higher GI? (Yang mana satu mempunyai kandungan GI yang lebih tinggi?)

Question 3




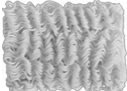
What's the GI for different types of rice? (Apakah nilai GI untuk berlainan jenis beras?)

Low GI: ≤ 55	Medium: 56-69	High: ≥ 70
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White rice (long grain/jasmine) (beras putih)	
	
Brown rice (beras perang)	
	
Japanese rice (sushi /Japanese cuisine) (beras sushi)	
	
Basmati (beras basmati/beriani)	




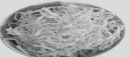


Question 4

Noodle or pasta? (Mee atau pasta)

	GI:
	GI:
	GI:
	GI:





Question 5

Which has lower GI? (Yang mana satu mempunyai GI yang lebih rendah?)

Answer question 1.


One bowl about 200gm. This is what makes up your bowl of rice-percentage of appropriate daily recommended intake in brackets for average adults.

				
	1 BOWL	2 BOWL	3 BOWL	4 BOWL
Energy	280kcal (12%)	560kcal (24%)	840kcal (36%)	1120kcal (48%)
Carbohydrate	62.2g (21%)	124.4g (41%)	186.6g (62.2%)	248.8g (83%)
Protein	5.6g (9%)	11.2g (17%)	16.8g (27%)	22.4g (35%)
Fats	1g (2%)	2g (3%)	3g (5%)	4g (9%)
GI	79	79	79	79
Glycaemic load	37	74	114	148

White rice has high GI of 79. What does that mean?

- GI : is a measure of how food containing carbohydrates raises blood sugar levels
- : ranges from 0 to 100 represent how quickly a person's blood sugar level rises after eating food containing carbohydrate
- : GI above 70 = high
- : GI below 55 = low

Answer question 2.



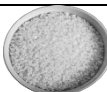
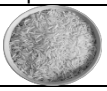
	
GI : 72 Glycaemic load : 4	GI : 63 Glycaemic load : 22

Not only GI is concern it also has to do with glycaemic load.

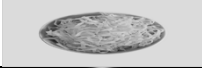
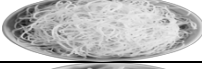


Watermelon has high GI of 72 but mostly water and has low GL of 4

In comparison coke low GI but high carbohydrate the GL is 5 times watermelon




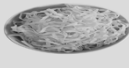


Answer question 3

	GI: 78
White rice (long grain/jasmine)	
	GI: 65(some with high GI but more fibre and phytochemicals)
Brown rice	
	GI: 75
Japanese rice (sushi /Japanese cuisine)	
	GI: 64(highly polished have higher GI)
Basmati	

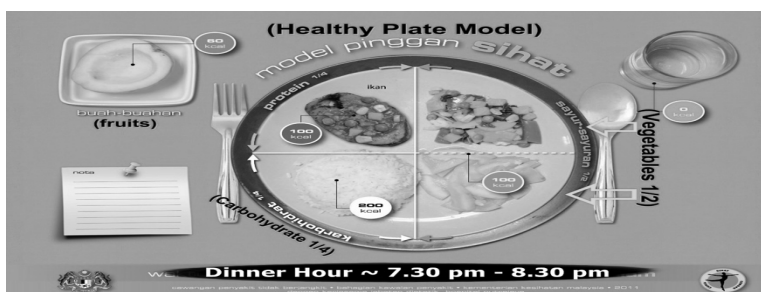
Answer question 4

	GI: 73
	GI: 58
	GI: 45
	GI: 47

Answer question 5

			
Processed food tends to have high GI but there are exceptions.			
			
Fat and protein content in the food helps to lower its GI.			
			

Unsweetened orange juice has a GI of 50, while whole fruit, un-juiced, has a slightly lower GI of 40. Soluble fibre helps to slow the absorption of glucose, and fruit juices have less fibre than whole fruit, raising their GI
(The whole (grain) truth about glycaemic index: Take our quiz, 2016)
 Appendix 7: Poster of Healthy Plate Model



(Intervensi Faktor Risiko NCD Dalam Komuniti : Komuniti Sihat Perkasa Negara, 2013)



Appendix 8: How to read food label
HOW TO UNDERSTAND FOOD LABELS?
BAGAIMANA UNTUK MEMAHAMI LABEL MAKANAN?
What to look for?
Apa yang perlu diperiksa?

If comparing nutrients in similar food use the per 100g column (Jika membandingkan makanan yang sama gunakan bahagian setiap 100g)

Sugar (Gula)
Try to avoid food with sugar content more than 15.0g per 100g (Elakkan makanan yang mengandungi gula lebih dari 15.0g setiap 100g)

Total fat (Jumlah garam)
Choose food with fat less 10g per 100g (Pilih makanan dengan kandungan lemak kurang 10g per 100g)

Saturated fat (Lemak tepu)
Aim for the lowest less than 3g per 100g (Sasarkan kepada jumlah paling rendah iaitu kurang 3g per 100g)

Salt
Food less than 0.3g per 100g are low in salt (Makanan kurang daripada 0.3g setiap 100g adalah rendah garam)

Nutrition Information (Maklumat Pemakanan)		
	Per serve (satu hidangan)	Per 100g (setiap 100g)
Serving size (saiz hidangan)	20g :5 piece (5 keping)	
Serving per package (hidangan setiap bungkus)	2	
Energy (Tenaga)	97kcal	486kcal
Carbohydrate (Karbohidrat)	13.8g	69.2g
Total sugar (Jumlah gula)	69	30.2g
Total fat (Jumlah lemak)	4.3g	21.4g
Salt/Sodium (Garam/Natrium)	0.069g	0.346g

- ❖ Be cautious of hidden sugar. For example, certain product stated no added sugar yet 10g of sugar were listed on the nutrition facts label. The reason for this is there are naturally occurring sugars present (lactose in milk). Beri perhatian terhadap gula tersembunyi. Sebagai contoh, terdapat produk menjelaskan tiada gula tambahan namun 10g gula ada tersenarai dalam maklumat pemakanan. Ini disebabkan terdapat gula semulajadi (laktosa dalam susu).
- ❖ As a person with diabetes, you must be concerned with calories and carbohydrates especially simple sugars that would affect your sugar control. Sebagai seorang penghidap diabetes, anda perlu mengambil berat tentang kalori dan karbohidrat terutamanya gula ringkas yang memberi kesan terhadap kawalan gula dalam darah anda.

Appendix 9: Poster of recommendations number of steps a day



Appendix 10: Diabetes Foot Ulcer Risk Assessment

Risk Factors	Yes	No
1. Foot ulcer (a wound that took > 2 weeks to heal) now or in the past		
2. Loss of sensation at any one site (determined after testing the 4 sites: great toe, first, third, and fifth metatarsal heads using the 10 gram/5.07 monofilament)		
3. Callus present on soles of feet or toes or abnormal foot shape (e.g., claw or hammer toes, bunion, obvious bony prominence, Charcot's foot or joint)		
4. Pedal pulses (dorsalis pedis or posterior tibial) not palpable and positive history of lower limb pain on exertion that is relieved with rest.		
5. Client unable to see the bottom of feet and/or unable to reach the bottom of feet and does not have someone who has been taught to perform appropriate foot care/inspection.		
6. Poor fitting footwear (shoes too narrow or short, no toe protection, rough or worn interior, uneven wear on sole or heel).		
7. Client has not received foot care education before.		
8. Client does not check condition of feet most days. Explore "How do you know if you have a reddened area or other problem with your feet?" or "How often do you check your feet?"		
9. Client does not report foot problems to health care provider. Explore "What would you do if you found a blister on your foot?"		
10. Client does not take steps to reduce risk of injury. Explore if client walks bare foot out or indoors, checks for foreign objects in shoes before wearing them, checks water temperature before entering a bath, etc.		
If the answer is NO to all items 1 – 4, the client is at	LOWER RISK	
If the answer is YES to any items 1-4, the client is at	HIGHER RISK	
If the answer is YES to any items 5 – 10, this indicates an opportunity to enhance self-care knowledge and behaviour.	SELF-CARE KNOWLEDGE DEFICIT	

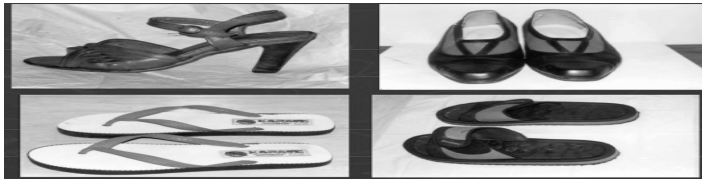
Adapted from: (Reducing Foot Complications for People with Diabetes Guideline supplement, Nursing Best Practice Guideline Shaping the future of Nursing, 2007)

Appendix 11: Do's and Don'ts Footwear

Do's Footwears



Don't Footwears



Appendix 12: Come on Six (by Tom Jackson's)

CONCEPT:

Stress is not something that usually comes on full force all at one time. In most cases it is a gradual building kind of thing that you hardly notice. Your stress might be caused by a number of things that build up or it could be just one future event which looms larger and larger the closer it gets. We could use a test at school as an example. When it is announced that you will be having a test in a couple of weeks you may feel some stress but two weeks seems like a long way off at the time. As the date of the test grows nearer, your stress level begins to increase and you may start exhibiting both physical and emotional signs of stress. This anticipation causes anxiety and increases the closer to the event you get.

MATERIALS NEEDED:

- 1 piece of paper per person
- 1 pencil or pen per group of five
- 1 dice per group

ACTIVITY:

Divide your group into groups of five. It is best if they are sitting around a table, but the activity can be played on the floor. Each person needs to have a piece of paper and each group needs to have one pen or pencil and one dice.

The activity works like this. Any person in the group may be the one to start by rolling the dice. The objective is to roll a six. Each person gets one roll of the dice to roll a six. If the person does not roll a six, then the dice is passed to the person on their left and they have one roll to try and get a six. This pattern continues until someone rolls a six. Upon rolling a six, that person takes the pencil and starts to number on their piece of paper from 1 to 100. (You can adjust this number for groups of varying abilities). The rules are that the numbers must be written one at a time, in consecutive order, and they must be legible. Have the person who is writing count out loud as they are writing each number. This tends to increase the excitement and stress of the activity. Everyone else keeps rolling the dice, skipping the person who is writing.

The person continues to write numbers until someone else in the group rolls a six. At this time, they must stop writing and give the pencil to that person who now begins to write. Remember that the dice continues around the table as the person is writing. When your turn to write is over, you once again take your turn rolling the dice. Each time an individual rolls a six, they continue to write numbers from where they left off. For example, if you had written numbers 1 to 15 on your first turn, then you would pick up with number 16 the next time you rolled a six. The round continues until someone in the group reaches 100.

Appendix 13: Deep breathing exercise

The following exercises are quick, easy relaxation techniques and breathing exercises for managing anxiety or if you are having difficulty sleeping.

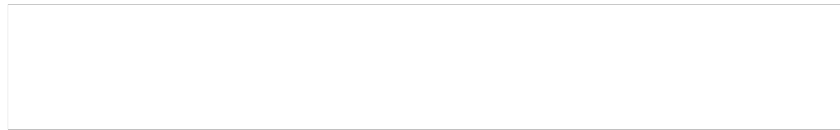
1. 7/11 breathing technique
 - a. take a deep breath in through your nose - try to do this to a count of 7
 - b. breathe out slowly through your mouth - try to do this to a count of 11
 - c. repeat 2 or 3 times.
2. Abdominal breathing
 - a. lie on your back with one hand on your chest and the other on your stomach
 - b. take a deep breath in so that you can feel your hand being pushed upwards by your stomach
 - c. notice how the chest then rises to push the other hand upwards
 - d. as you slowly breathe out notice your hands then follow the chest and stomach back down
 - e. repeat 2 or 3 times.
3. Positive suggestions
 - a. close your eyes
 - b. take a few deep breaths consciously to slow down your breathing
 - c. repeat the following directions silently over and over in your mind "I will feel more & more confident each day" or "I will feel calmer each day" or "I will feel more in control each day".

4. Deep breathing exercise
 - a. take a deep breath in and hold it to a count of 5
 - b. as you breathe out slowly through your mouth think of the word 'relax'
 - c. Take another deep breath in to a count of 5
 - d. as you breathe out say to yourself 'relax'
 - e. repeat the above for a total of 5 deep breaths

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Appendix B



Arbaktun Mohamed

23 December 2015

Dear Arbaktun ,

Study Title: Diabetes education programme using motivational interviewing (MY DEUMI) for People Newly Diagnosed with Type 2 Diabetes Mellitus (T2DM) in Malaysia: A pilot study

Study Reference: HR-15/16-2009

I am pleased to inform you that full approval for your project has been granted by the Psychiatry, Nursing and Midwifery Research Ethics Subcommittee

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (<http://www.kcl.ac.uk/college/policyzone/index.php?id=247>).

For your information, ethical approval is granted until 23rd December 2018. If you need approval beyond this point, you will need to apply for an extension at least two weeks before this. You will be required to explain the reasons for the extension. However, you will not need to submit a full re-application unless the protocol has changed. If you have been granted approval for only 12 months, you will not be sent a reminder when it is due to lapse.

Ethical approval is required to cover the data-collection phase of the study. This will be until the date specified in this letter. However, you do not need ethical approval to cover subsequent data analysis or publication of the results.

For secondary data-analysis, ethical approval is applicable to the data that is sensitive or identifies participants.

Approval is applicable to period in which such data is accessed or evaluated.

Please note you are required to adhere to all research data/records management and storage procedures agreed to as part of your application. This will be expected even after the completion of the study.

If you do not start the project within three months of this letter, please contact the Research Ethics Office.

Please note that you will be required to obtain approval to modify the study. This also encompasses extensions to periods of approval. Please refer to the URL below for further guidance about the process:

<http://www.kcl.ac.uk/innovation/research/support/ethics/applications/modifications.aspx>

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact the Research Ethics Office:

(<http://www.kcl.ac.uk/innovation/research/support/ethics/contact.aspx>)

We wish you every success with this work.

Yours sincerely,

James Patterson - Senior Research Ethics Officer

For and on behalf of

Professor Gareth Barker, Chair of the Psychiatry, Nursing and Midwifery Research Ethics Subcommittee

Cc: Kirsty Winkley

Appendix C



JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 KUALA LUMPUR



Tel.: 03-2287 4032/2282 0491/2282 9085
03-2282 9082/2282 1402/2282 1449
Faks: 03-2282 0015

Ruj. Kami : (5) KKM/NIHSEC/P16-233
Tarikh : 24hb Februari 2016

ARBAKTUN MARDIAH BINTI MOHAMED
INSTITUTE OF PSYCHIATRY, PSYCHOLOGY AND NEUROSCIENCE
KING'S COLLEGE OF LONDON

TUAN/PUAN,

NMRR-15-2200-27537 (IIR)
DIABETES EDUCATION PROGRAMME USING MOTIVATIONAL INTERVIEWING (MY DEUMI) FOR PEOPLE NEWLY DIAGNOSED WITH TYPE 2 DIABETES MELLITUS (T2DM) IN MALAYSIA: A PILOT STUDY.

Lokasi Kajian: KLINIK KESIHATAN MAHMOODIAH
KLINIK KESIHATAN TAMPOI

Dengan hormatnya perkara di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia (KKM) tiada halangan, dari segi etika, ke atas pelaksanaan kajian tersebut. JEPP mengambil maklum bahawa kajian tersebut hanya melibatkan pengumpulan data menggunakan **kaedah temubual dan structured group education programme** sahaja.

3. Segala rekod dan data subjek adalah **SULIT** dan hanya digunakan untuk tujuan kajian ini dan semua isu serta prosedur mengenai *data confidentiality* mesti dipatuhi.

4. **Kebenaran daripada Pegawai Kesihatan Daerah/Pengarah Hospital dan Ketua-Ketua Jabatan atau pegawai yang bertanggungjawab disetiap lokasi kajian di mana kajian akan dijalankan mesti diperolehi sebelum kajian dijalankan.** Dato'/Dr/ Tuan/ Puan perlu akur dan mematuhi keputusan tersebut. Sila rujuk kepada garis panduan Institut Kesihatan Negara mengenai penyelidikan di Institusi dan fasiliti Kementerian Kesihatan Malaysia (Pindaan 01/2015) serta lampiran *Appendix 5* untuk templet surat memohon kebenaran tersebut.

5. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga **23hb Februari 2017**. Dato'/Dr./ Tuan/ Puan perlu menghantar perkara-perkara berikut kepada JEPP selepas mengikut kesesuaian. Borang-borang berkaitan boleh dimuat turun daripada laman web MREC (<http://www.nih.gov.my/mrec>).

Appendix D

Phase 3

1. Title of study: Diabetes education programme using motivational interviewing (MY DEUMI) for people newly diagnosed with type 2 diabetes mellitus (T2DM) in Malaysia : A pilot study
2. Name of investigator and institution: Arbaktun Mardiah Binti Mohamed and Klinik Kesihatan Mahmoodiah Johor Bahru/ Klinik Kesihatan Tampoi Johor Bahru
3. Name of sponsor: Program Pascasiswazah Majlis Amanah Rakyat (PascaMARA) and Institute of Psychiatry, Psychology and Neuroscience King's College London

4. Introduction:

You are invited to participate in a research study because you have been diagnosed with type 2 diabetes mellitus (T2DM) in the past 60 months that requires diabetes self-management education. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the researcher if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide your researcher with information on your health history.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. What is the purpose of the study?

The purpose of this study to test out (pilot) a new structured education program using motivational interviewing. It is specifically for people newly diagnosed with T2DM and their families or friends. We need to conduct the study with people newly diagnosed with T2DM in order to address our research questions. We would like to see if we could help you to reduce the complications risk by increasing your confidence in self-management. Therefore, we are inviting you to take part in this research study.

Motivational interviewing (MI) is a therapy that involves talking about your thoughts and feelings to help you make positive changes to your life. The researcher aims to help people with diabetes to be more confident, willing and committed to making changes to their lifestyle will provide this intervention. We would also like to test whether group based education and motivational interviewing can help people to improve self-management of their disease such as reducing the risk of diabetes complication. Uncontrolled blood sugar level may increase your chances of developing complications such as heart disease, kidney disease, eyes problems and neurological deficit (nerve problems). Most of us aware that we should be eating healthily and be more active but for many people it can be very difficult to achieve this for different reasons.

6. What kind of study procedures will I receive?

If you agree to participate in the study, the researcher assistant would like to meet with you and take some measurements. This appointment will involve:

- Measuring your height, weight, waist circumference and blood pressure.
- Questionnaires: Self-reported of self-efficacy and diabetes self-management using Diabetes Management Self-Efficacy Scale United Kingdom (DMSES UK) and Diabetes Self-Management Questionnaire (DSMQ).

All the participants will be invited for a group education session as detailed below:

1. Group education sessions

- i. If you are invited you will be given an appointment to see a facilitator with a few other participants. The facilitator will deliver the sessions at your primary clinic or a local community venue.
- ii. During the study you will receive 10-12 hour sessions of group education.

7. What will happen if I decide to take part?

Everybody will continue to have their usual care from their physician and follow up appointment from the primary clinic.

All participants will meet the researchers after 3 months to 4 months to repeat the measurements taken in the first appointment. The aim of this study is to understand how useful motivational interviewing and group education is in self-management of people with T2DM. To help us understand what happens during the education sessions therefore, we would like to audio record the education sessions. Any sessions that recorded will be kept anonymous throughout the analysis process. During the course of the study you might be invited to discuss your thoughts and experiences of the education sessions that you have received.

8. When will I receive the trial product and how should it be kept?

You will be given a personal diabetes diary. You must not give the product to anyone else. The researcher will instruct you on how to fill in the diary. Please ensure that you keep your diary after you have finished with them.

9. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the researcher honestly and completely. If your condition or circumstances change during the study, you must tell the researcher. You must inform your researcher immediately if you make any changes to any of your current treatments, even those which you have been taking for a long time.

10. What kind of treatment will I receive after my participation in the trial?

No study product will be given to you at the end of your participation in the study.

11. What are the potential risks and side effects of being in this study?

We do not expect there to be any disadvantages of participating in the study. The education sessions are based on information regarding T2DM, eating more healthily, increasing physical activity, gradual and sustainable weight loss.

12. What are the benefits of being in this study?

They are no proven benefits to taking part in this research but you may receive the education sessions using motivational interviewing that might give health benefits in term of self-management information as it has been shown in other research it is related to better outcomes. The results of our research could also help to develop new effective education programme for people with T2DM in Malaysia.

13. What if I am injured during this study?

If you are injured as a result of being in this study, you should contact your study researcher. In the event of a bodily injury or illness directly resulting from the education sessions the sponsor will pay for reasonable and necessary treatment. The sponsor is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or willful misconduct, the negligence or willful misconduct of your researcher or the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

14. Who is funding the research?

This study is a PhD thesis project sponsored by Majlis Amanah Rakyat who will pay for the scholarship to the researcher. All other drugs and procedures that are not required by the study but are part of your routine medical care will have to be paid by you or your insurance.

15. Can the research or my participation be terminated early?

The study researcher may due to concerns for your safety, stop the study or your participation at any time. If the study is stopped early for any reason you will be informed.

16. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study will be archived and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time.

17. Who should I call if I have questions?

If you have any questions or require more information about this study, please contact me using the following contact details:

Arbaktun Mardiah Mohamed
MPhil/PhD Candidate in Psychological Medicine Research
Dept. of Psychological Medicine
Institute of Psychiatry, Psychology and Neuroscience
King's College of London
Weston Education Centre
10 Cutcombe Road
London, SE5 9RJ
Tel: 013-8815045
E-mail: arbaktun.mohamed@kcl.ac.uk

If this study has harmed, you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information:

Kirsty Winkley PhD
Lecturer in Diabetes and Psychology,
South London CRN, Diabetes, Metabolism & Endocrine Specialty Group Lead
Dept. of Psychological Medicine,
Institute of Psychiatry, Psychology and Neuroscience
Weston Education Centre
Cutcombe Road
London
SE5 9RJ
+44 (0)20 7848 5664
Email: kirsty.1.winkley@kcl.ac.uk

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287 4032.

Appendix E

INFORMED CONSENT FORM

Title of Study: **Diabetes education programme using motivational interviewing (MY DEUMI)** for people newly diagnosed with type 2 diabetes mellitus (T2DM) in Malaysia: A pilot study

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as **STRICTLY CONFIDENTIAL**
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.

Subject:

Signature:

I/C number:

Name:

Date:

Investigator conducting informed consent:

Signature:

I/C number:

Name:

Date:

Impartial witness: *(Required if subject is illiterate and contents of participant information sheet is orally communicated to subject)*

Signature:

I/C number:

Name:

Date:

Appendix F

Evaluation Form (MY DEUMI Programme)

Please evaluate the programme by respond to each of the following domains using the scale below. Please tick (/) the box that indicate your response to your experience.

Domain		Excellent	Good	Moderate	Fair	Poor
Facilitator	Knowledgeable					
	Clear and concise					
	Time management					
	Two-way communication					
Topic	Important and relevant					
Materials	Quality					
	Easy to understand					
Time management	Question and answer session					
	Hands-on session					
	Evaluation					
Objective	Explained					
	Achieved					
Domain		Extremely likely	Likely	Neutral	Unlikely	Extremely unlikely
Output of the programme	I will do changes in future					
	I will use the provided materials					
	I will search for extra information					

Appendix G

FIDELITY ASSESSMENT: Fidelity score sheet.

Legend:	
Scale 1: Was the session delivered as written?	1. Not at all closely 2. Moderately closely 3. Very closely
Scale 2: Were one or more activities shortened?	1. All activities were shortened 2. Some activities were shortened 3. No activities were shortened

Session	Intervention component	Scale 1: Was the session delivered as written?			Scale 2: Were one or more activities shortened?		
Introduction 1: Are you ready?	1. Introduction to the whole programme: <ul style="list-style-type: none"> Ground rule Programme approach 2. Exploring participants hope	1	2	3	1	2	3
Introduction 2: Towards an effective self-management	1. Sharing moments: <ul style="list-style-type: none"> Risk factors of T2DM Individuals ways to control sugar levels 2. Eliciting change talk: <ul style="list-style-type: none"> Benefits of lifestyle changes 3. Individual assessment: <ul style="list-style-type: none"> Diabetes knowledge quiz 	1	2	3	1	2	3
Session 1: What is diabetes?	1. Exploring the understanding of the disease process: <ul style="list-style-type: none"> Feedback from the visual aid (Poster Malaysian at risk!) Match the boxes to label (Normal food digestion process) Group discussion regarding insulin regulation Complete diagram for the complications that they might face or already experience 2. Eliciting change talk: <ul style="list-style-type: none"> Reason to reduce the complications 3. Goal setting: <ul style="list-style-type: none"> Effective goal setting techniques Discuss in pairs and write personal goal 	1	2	3	1	2	3
Session 2: A sweet through time	1. Exploring views: <ul style="list-style-type: none"> Reflection of visual aid (figure of adults who died from diabetes, 	1	2	3	1	2	3

Session	Intervention component	Scale 1: Was the session delivered as written?			Scale 2: Were one or more activities shortened?		
	<p>HIV/AIDS, tuberculosis and malaria).</p> <ul style="list-style-type: none"> • Reflection of the figure how many risk of complications can be reduced every reduction of HBA1c (% or mmol/mol). • Discussion regarding type of food or drinks that is recommended. <p>2. Low glycaemic index diet quiz.</p> <p>3. Method to reduce the carbohydrate intake</p> <p>4. Exploring perspectives:</p> <ul style="list-style-type: none"> • Activity called “good and not so good things” (what is good about eating rice and not so good consuming too much of rice?) <p>5. Exploring barriers in healthy eating and ways to overcome it.</p> <p>6. Goal setting: discuss in pairs</p>						
Session 3: Diabetes medicine guide	<p>1. Exploring view:</p> <ul style="list-style-type: none"> • Myth or fact about insulin • Sharing moments of prescribed medicine and how the medicine works <p>2. Offer information regarding insulin action</p> <p>3. Exploring value regarding fearful of insulin through discussion regarding the beneficial value of it.</p> <p>4. Reflection: the importance of this session.</p>	1	2	3	1	2	3
Session 4: Keep calm and let's play	<p>Activity 1 (Food labels)</p> <ul style="list-style-type: none"> • Recommended amount of carbohydrate, fat and salt per day. • How to read label (handout) • Read label from the display food package. <p>Activity 2 (Sugar game)</p> <ul style="list-style-type: none"> • Calculate the number of teaspoons of sugar contained in local food product and mainly consumed by Malaysian. • Reflections of the amount sugar of each drinks and foods. <p>Activity 3 (review pedometer).</p> <ul style="list-style-type: none"> • How to use a pedometer. 	1	2	3	1	2	3

Session	Intervention component	Scale 1: Was the session delivered as written?			Scale 2: Were one or more activities shortened?		
Session 5: Let's move! To stay healthy and lose weight	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> Sharing moments of successful experience in weight lost. Recommendation for physical activity. Eliciting change talk: <ul style="list-style-type: none"> Reason walking as a form of exercise. Exploring barriers and ways to increase physical activity. 	1	2	3	1	2	3
Session 6: Keep calm and keep walking!	<ol style="list-style-type: none"> Exploring view through reflections of visual aid (activity to burn calories). Broadening perspectives: My typical day and opportunity to increase number of steps. Into actions: tools and type of activity. Activity: walking around seminar room and measure the total of burn calories. Goal setting: Individual target (number of steps a day). 	1	2	3	1	2	3
Session 7: Diabetes foot	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> Reflection of visual aid (diabetes foot ulcer) and ways to reduce the risk Activity 1: Risk assessment (diabetes foot ulcer risk assessment questionnaire) Activity 2: Step-by-step daily foot care. Reflection of whole session. 	1	2	3	1	2	3
Session 8: Dealing with diabetes	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> Individual activity: Feeling identification. Group activity: The importance of stress management. Activity and reflection 1: Motivational came named 'Come on Six by Tom Jackson's) Activity and reflection 2: Stress level measurement and ways to reduce anxiety or stress. Activity 3: Deep breathing technique. 	1	2	3	1	2	3
Session 9: Complementary and alternative medicine (CAM)-Herbal medicine	<ol style="list-style-type: none"> Exploring view: <ul style="list-style-type: none"> To assess the number of participants interested using CAM (herbal medicine). Group discussion: How CAM helps in diabetes management. Activity 1: Discuss in pairs how the used herbal medicine works. 	1	2	3	1	2	3

Session	Intervention component	Scale 1: Was the session delivered as written?			Scale 2: Were one or more activities shortened?		
	3. Providing information: List of herbs used for T2DM (How it works and potential side effects). 4. Reflection of whole session.						
Session 10: Relapse prevention	2. Broadening perspectives: Case study 3. Activity 1: Discuss in pairs how lapse change to relapse. 4. Activity 2: Inspiration and motivation (group members' strength or someone from outside of group) 5. Activity 3: Confidence ruler and ways to increase confidence. 6. Reflection of whole session	1	2	3	1	2	3
Session 11: Closing	1. Exploring view: What they have gained throughout the programme. 2. Evaluation: Discuss in pairs the most enjoyable and helpful activity. 3. Summary and closing: reminder of telephone follow up and 12-week review of glycaemic control.	1	2	3	1	2	3